US011779461B2

(12) **United States Patent**
Essinger et al.

(10) **Patent No.: US 11,779,461 B2**
(45) **Date of Patent: Oct. 10, 2023**

(54) **CATHETER DELIVERY SYSTEM FOR STENT VALVE**

(71) Applicant: **Symetis SA**, Ecublens (CH)

(72) Inventors: **Jacques Essinger**, Wollerau (CH); **Stephane Delaloye**, Bülach (CH); **Jean-Luc Hefti**, Cheseaux-Noréaz (CH); **Luc Mantanus**, Lausanne (CH)

(73) Assignee: **Symetis SA**, Ecublens (CH)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 882 days.

(21) Appl. No.: **16/670,117**

(22) Filed: **Oct. 31, 2019**

(65) **Prior Publication Data**

US 2020/0129293 A1 Apr. 30, 2020

Related U.S. Application Data

(63) Continuation of application No. 15/588,498, filed on May 5, 2017, now abandoned, which is a continuation
(Continued)

(30) **Foreign Application Priority Data**

Sep. 10, 2010 (EP) 10176263

(51) **Int. Cl.**
A61F 2/00 (2006.01)
A61F 2/24 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61F 2/2436*** (2013.01); ***A61B 90/08*** (2016.02); ***A61F 2/2418*** (2013.01);
(Continued)

(58) **Field of Classification Search**
None
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,905,012 A 9/1959 Lohr
5,030,204 A 7/1991 Badger
(Continued)

FOREIGN PATENT DOCUMENTS

EP 1358903 A2 11/2003
EP 1380271 A1 1/2004
(Continued)

OTHER PUBLICATIONS

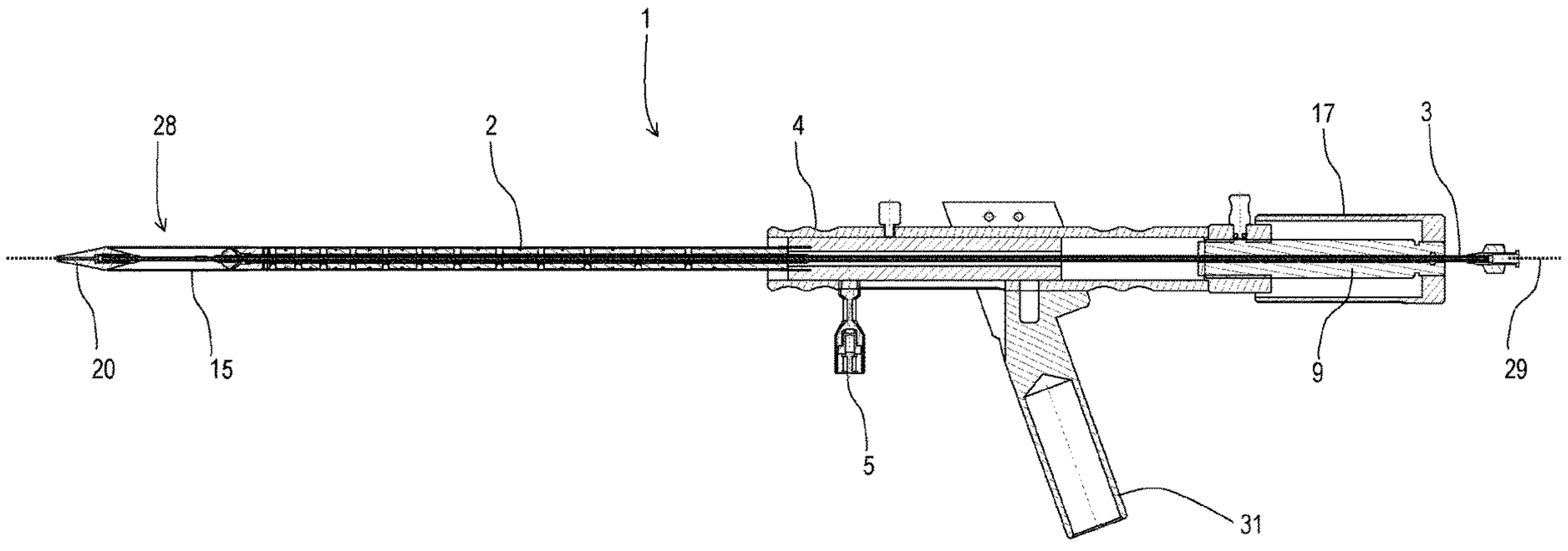
International Search Report for International Application No. PCT/EP2011/065620, date of completion of report Apr. 11, 2012.
(Continued)

Primary Examiner — Steven O Douglas
(74) *Attorney, Agent, or Firm* — Seager, Tufte & Wickhem LLP

(57) **ABSTRACT**

A delivery catheter for a stent. The delivery catheter may comprise a distal end and a proximal end. The distal end includes a stent attachment region adapted to receive a stent. The stent may be of the self-expanding type. The catheter further comprises a handle at its proximal end and at least one sheath which may at least partially circumferentially cover said stent such as to retain it in a collapsed configuration. The sheath is coupled at its proximal end to an actuator located on said handle portion.

13 Claims, 7 Drawing Sheets



Related U.S. Application Data

of application No. 13/821,434, filed as application No. PCT/EP2011/065620 on Sep. 9, 2011, now Pat. No. 9,675,485.

(60) Provisional application No. 61/431,333, filed on Jan. 10, 2011.

(51) **Int. Cl.**
A61B 90/00 (2016.01)
A61F 2/95 (2013.01)

(52) **U.S. Cl.**
CPC *A61B 2090/0811* (2016.02); *A61F 2/9517* (2020.05); *A61F 2250/0097* (2013.01)

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,776,142	A	7/1998	Gunderson	
5,782,909	A	7/1998	Quiachon	
5,906,619	A	5/1999	Olson et al.	
5,957,949	A	9/1999	Leonhardt et al.	
6,203,550	B1	3/2001	Olson	
6,258,064	B1	7/2001	Smith	
6,551,302	B1	4/2003	Rosinko	
6,582,459	B1	6/2003	Lau	
6,585,694	B1	7/2003	Smith	
6,669,716	B1	12/2003	Gilson	
7,320,702	B2	1/2008	Hammersmark	
7,615,044	B2	11/2009	Scheibe	
7,722,663	B1	5/2010	Austin	
8,382,826	B2	2/2013	Taylor	
8,858,495	B2	10/2014	Tegg	
9,155,619	B2	10/2015	Liu	
9,364,314	B2 *	6/2016	Berra	A61F 2/064
2003/0009132	A1	1/2003	Schwartz	
2003/0074045	A1	4/2003	Buzzard	
2003/0153874	A1	8/2003	Tal	
2003/0191516	A1	10/2003	Weldon	
2003/0199916	A1	10/2003	Yee	
2003/0199966	A1	10/2003	Shiu	
2005/0027305	A1	2/2005	Shiu	
2005/0080476	A1	4/2005	Gunderson	
2005/0137688	A1	6/2005	Salahieh et al.	
2005/0149159	A1	7/2005	Andreas	
2005/0222603	A1	10/2005	Andreas	
2005/0228475	A1	10/2005	Keeble	
2005/0288766	A1	12/2005	Plain	
2006/0282150	A1	12/2006	Olson	
2007/0043435	A1	2/2007	Seguin et al.	
2007/0255390	A1	11/2007	Ducke	
2007/0282250	A1	12/2007	Anderson	
2008/0114435	A1	5/2008	Bowe	
2008/0114444	A1	5/2008	Yu	
2008/0200943	A1	8/2008	Barker	
2008/0255542	A1	10/2008	Nimgaard	
2008/0262430	A1	10/2008	Anderson	
2008/0262590	A1	10/2008	Murray	
2008/0294111	A1	11/2008	Tal	
2009/0221961	A1	9/2009	Tal	
2009/0254165	A1 *	10/2009	Tabor	A61F 2/844 623/1.11
2009/0281524	A1	11/2009	Scheibe	
2010/0030237	A1	2/2010	Hayashi	
2010/0030255	A1	2/2010	Berra	
2010/0121434	A1	5/2010	Paul	
2010/0174290	A1 *	7/2010	Wuebbeling	A61F 2/966 606/108
2011/0270371	A1	11/2011	Argentine	
2011/0282425	A1	11/2011	Dwork	
2011/0307049	A1 *	12/2011	Kao	A61F 2/966 623/1.11
2012/0123528	A1	5/2012	Knippel	
2012/0221091	A1	8/2012	Hartly	
2013/0231736	A1	9/2013	Essinger	
2013/0274708	A1	10/2013	Phillips	
2014/0171873	A1	6/2014	Mark	
2016/0184023	A1	6/2016	Grace	
2016/0184570	A1	6/2016	Grace	

FOREIGN PATENT DOCUMENTS

WO	9904728	A1	2/1999
WO	0112256	A1	2/2001
WO	2008138584	A1	11/2008
WO	2009053497	A1	4/2009
WO	2009137359	A1	11/2009
WO	2011051043	A1	5/2011
WO	2012026965	A2	3/2012

OTHER PUBLICATIONS

Extended European Search Report for Application No. 23157239.7 dated May 11, 2023.

* cited by examiner

FIG. 1

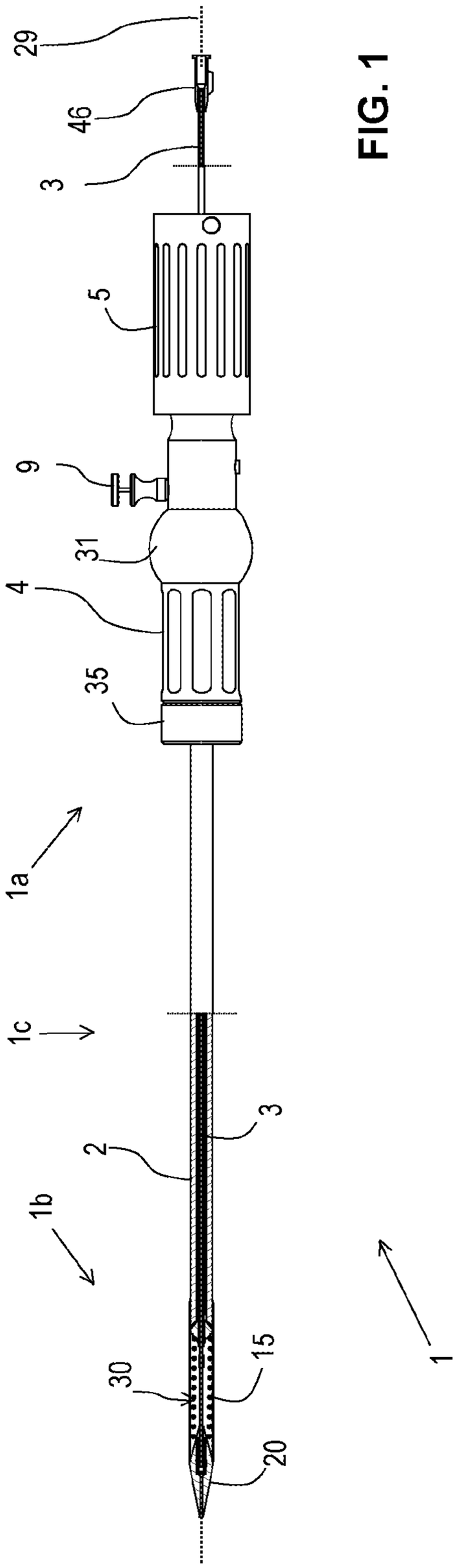
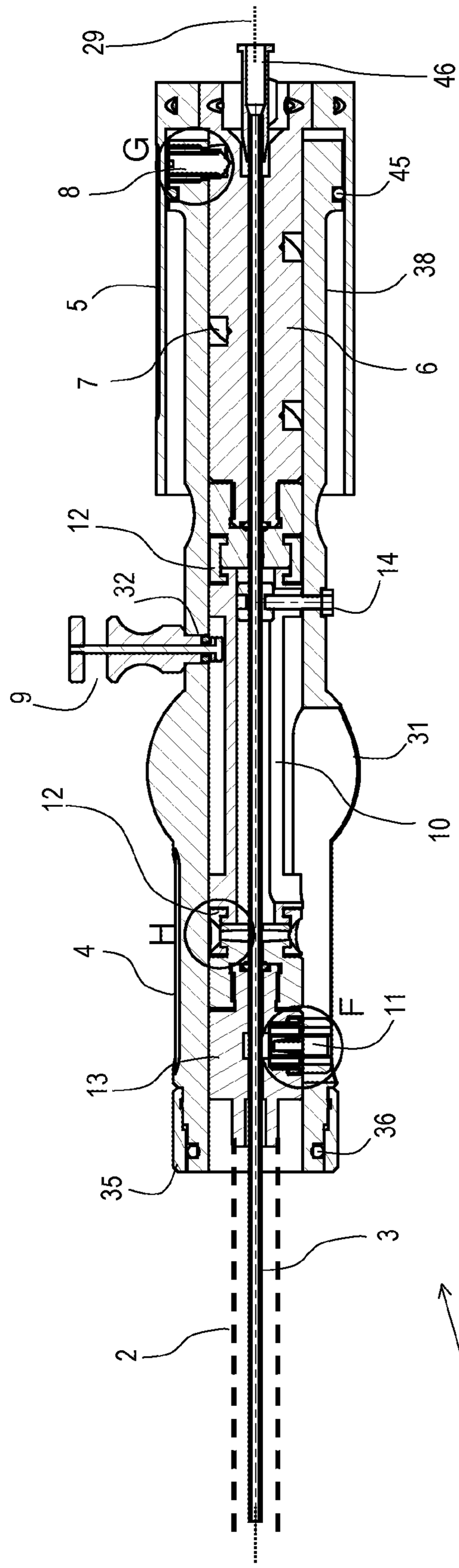

29
46
3
5
9
31
4
35
1a
1c
1b
2
3
30
15
20
1

FIG. 2


29
46
G
8
45
5
38
7
6
12
14
32
9
31
12
10
H
4
F
11
13
36
35
3
2
1a

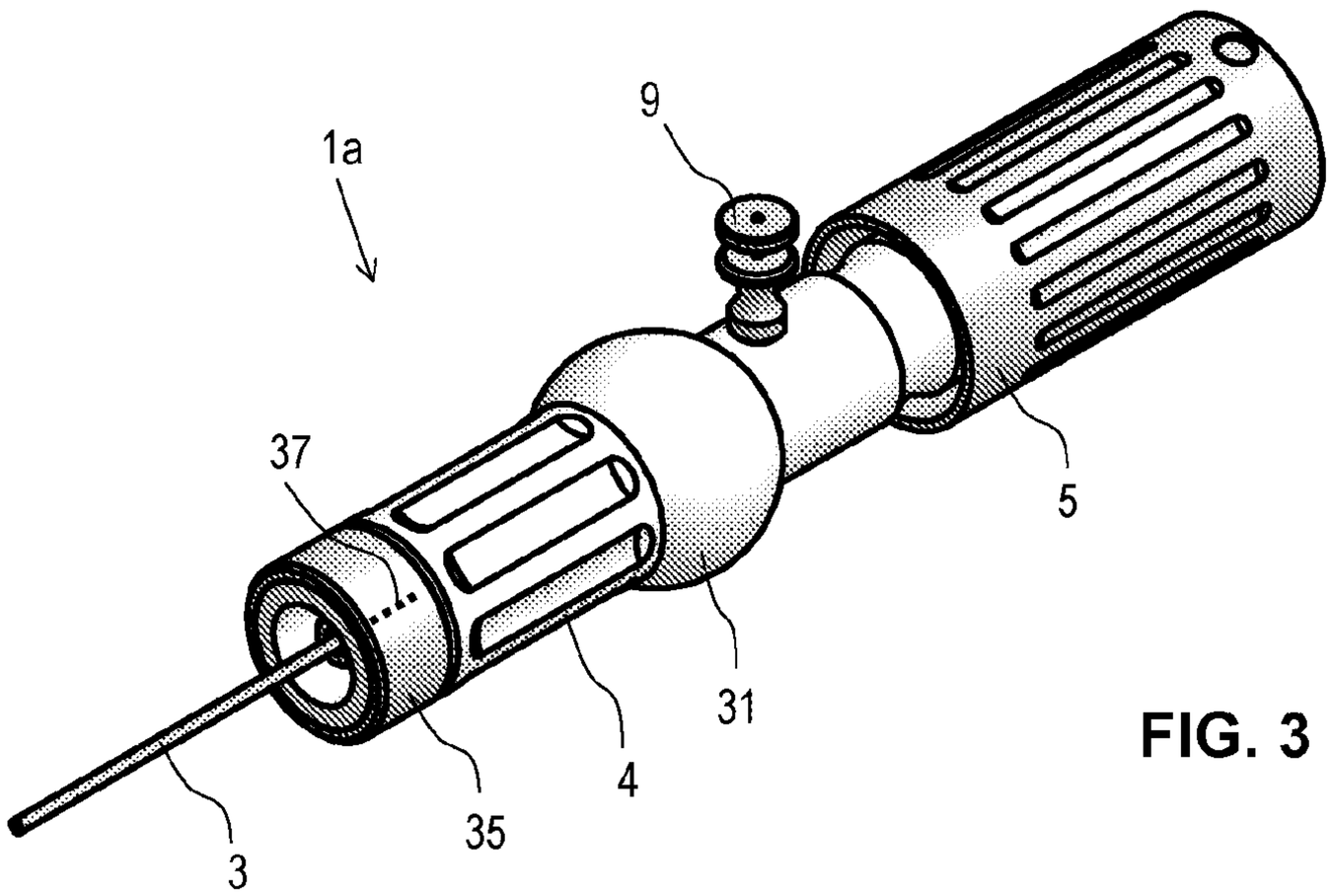


FIG. 3

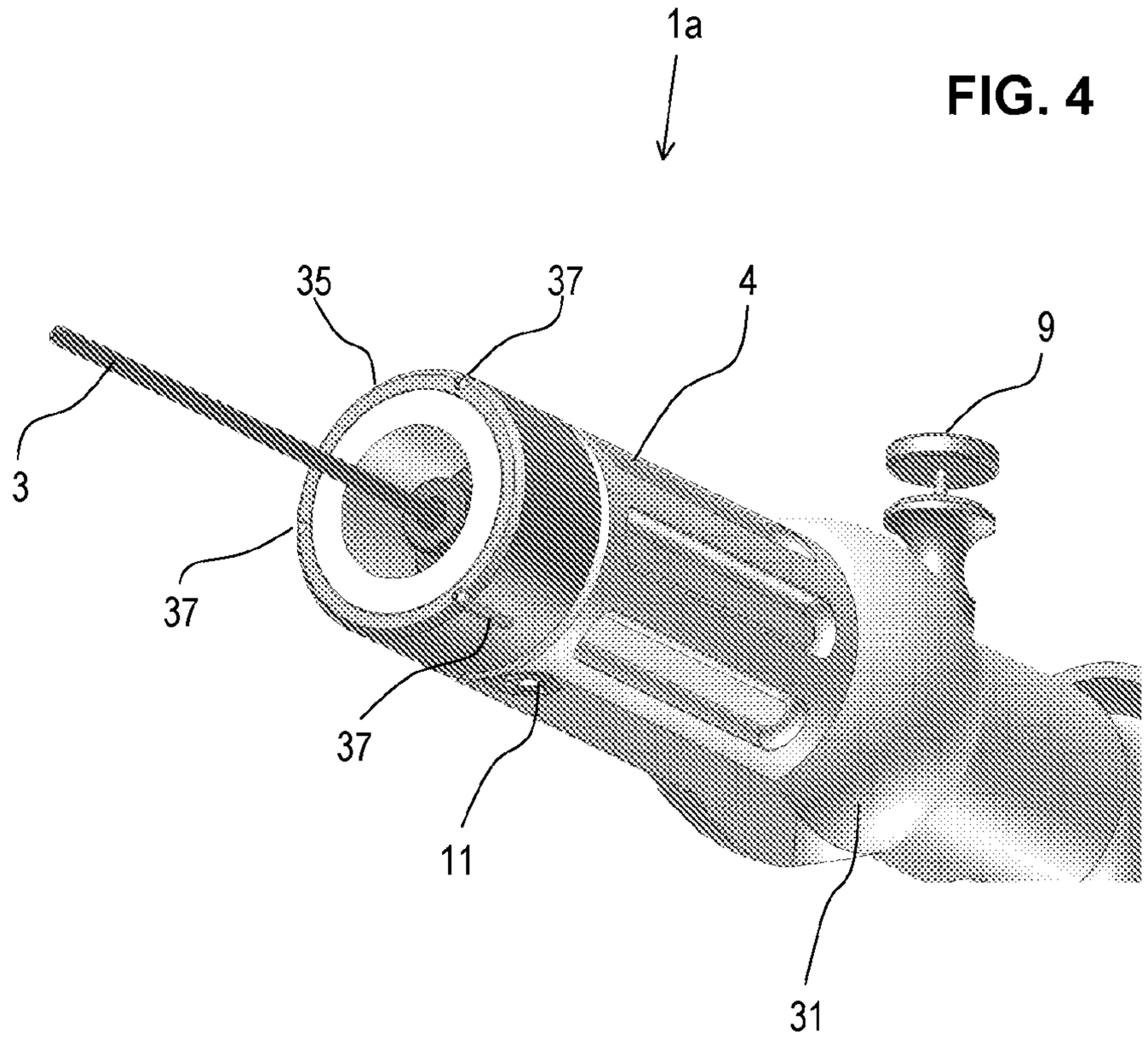


FIG. 4

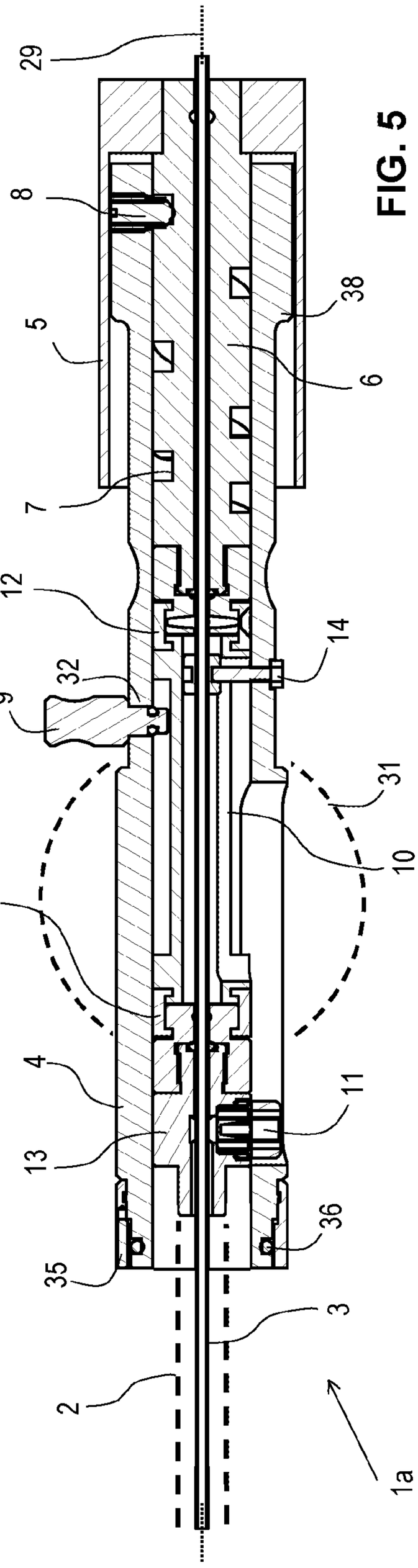
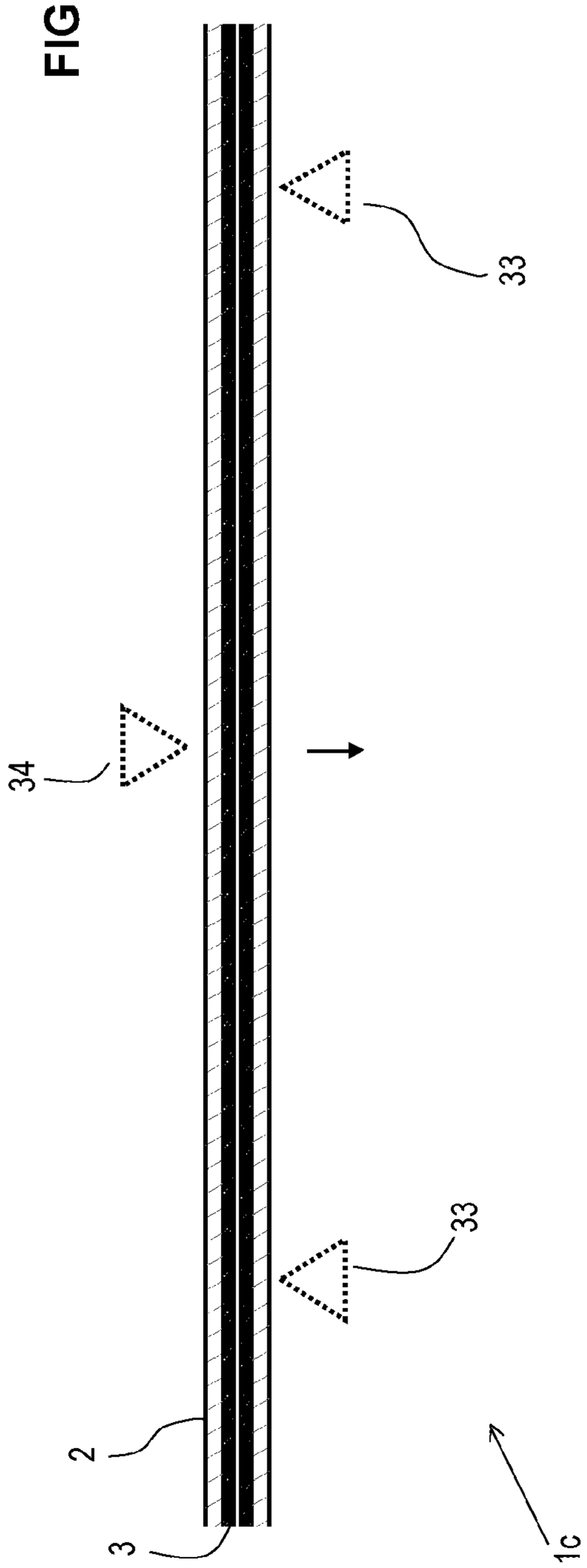


FIG. 5

FIG. 6



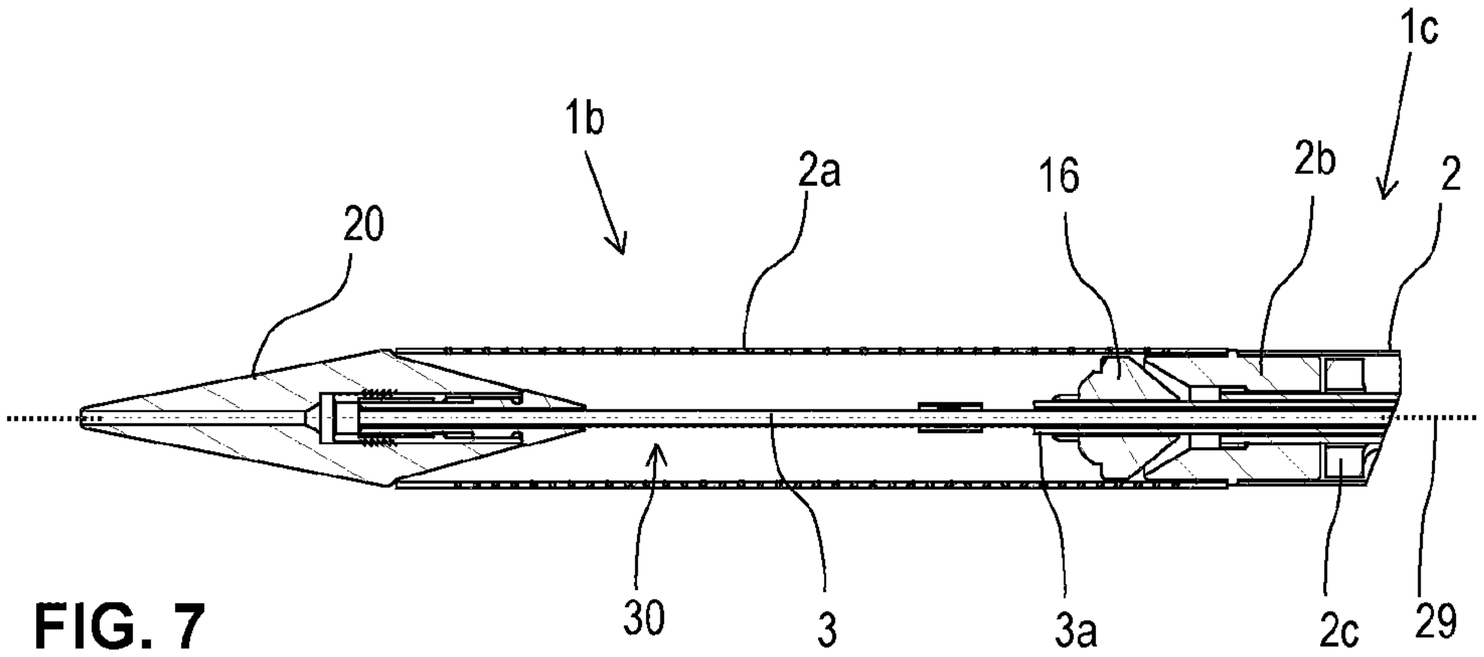


FIG. 7

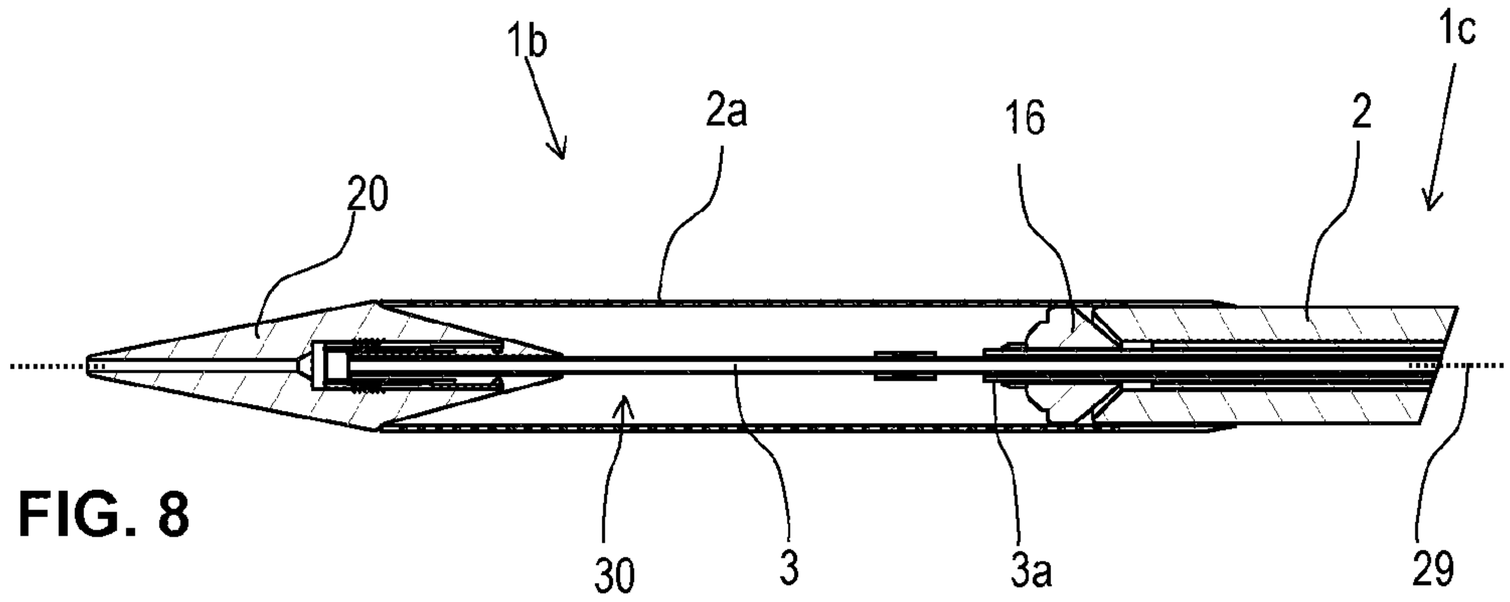


FIG. 8

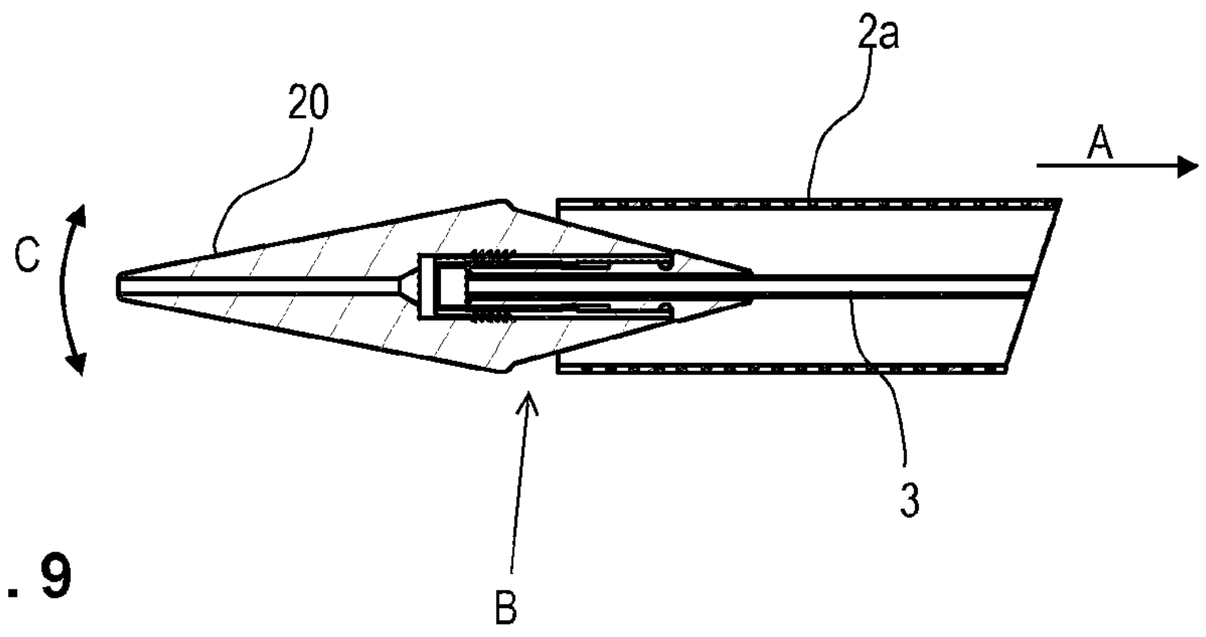


FIG. 9

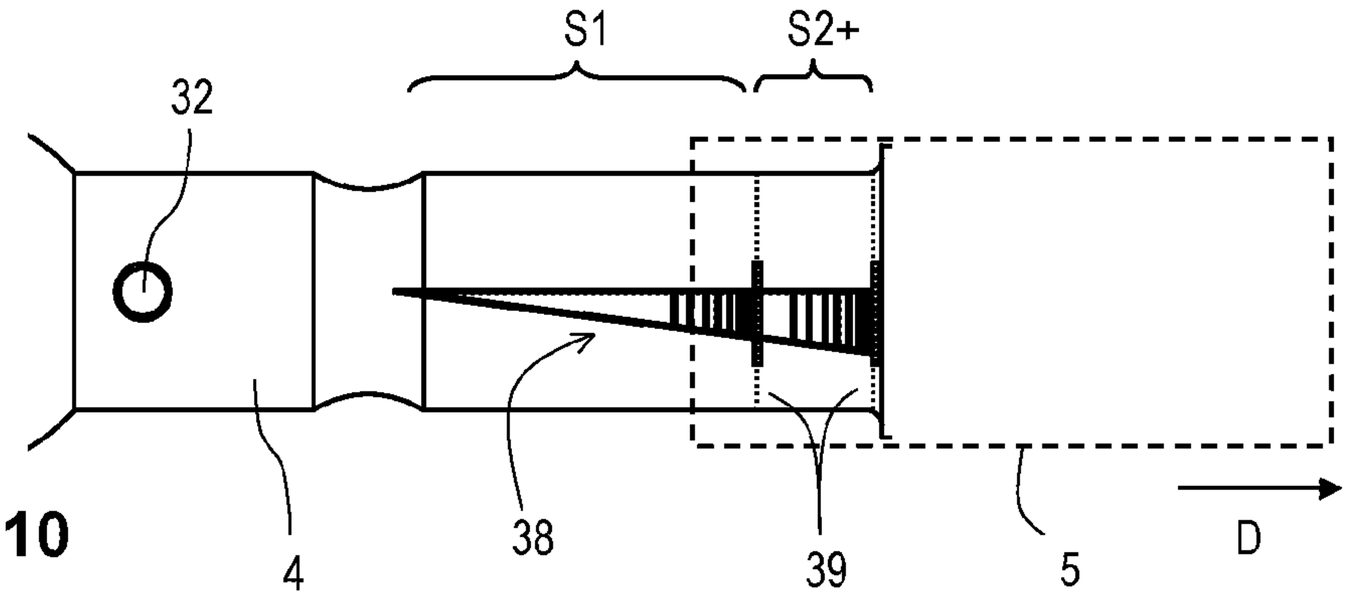


FIG. 10

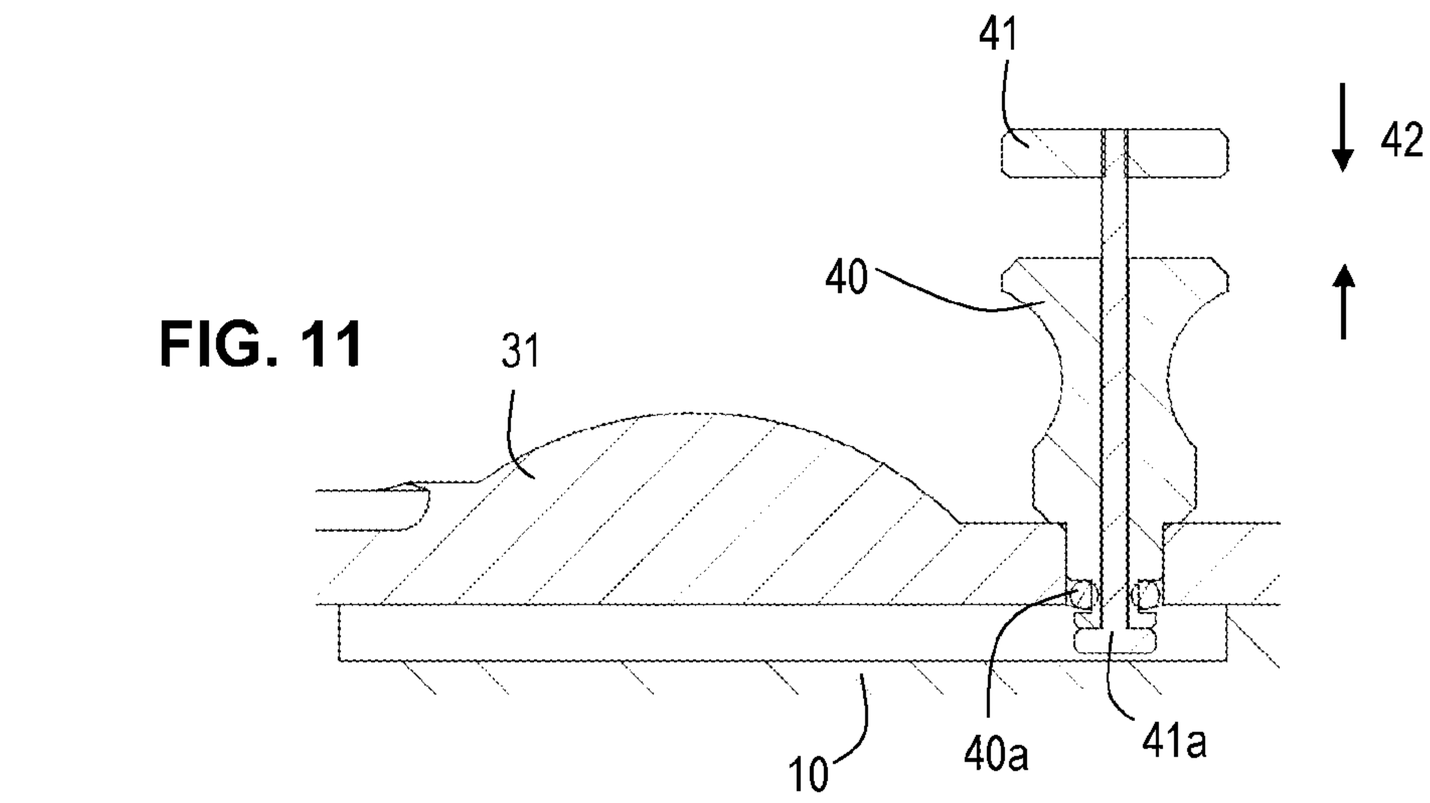


FIG. 11

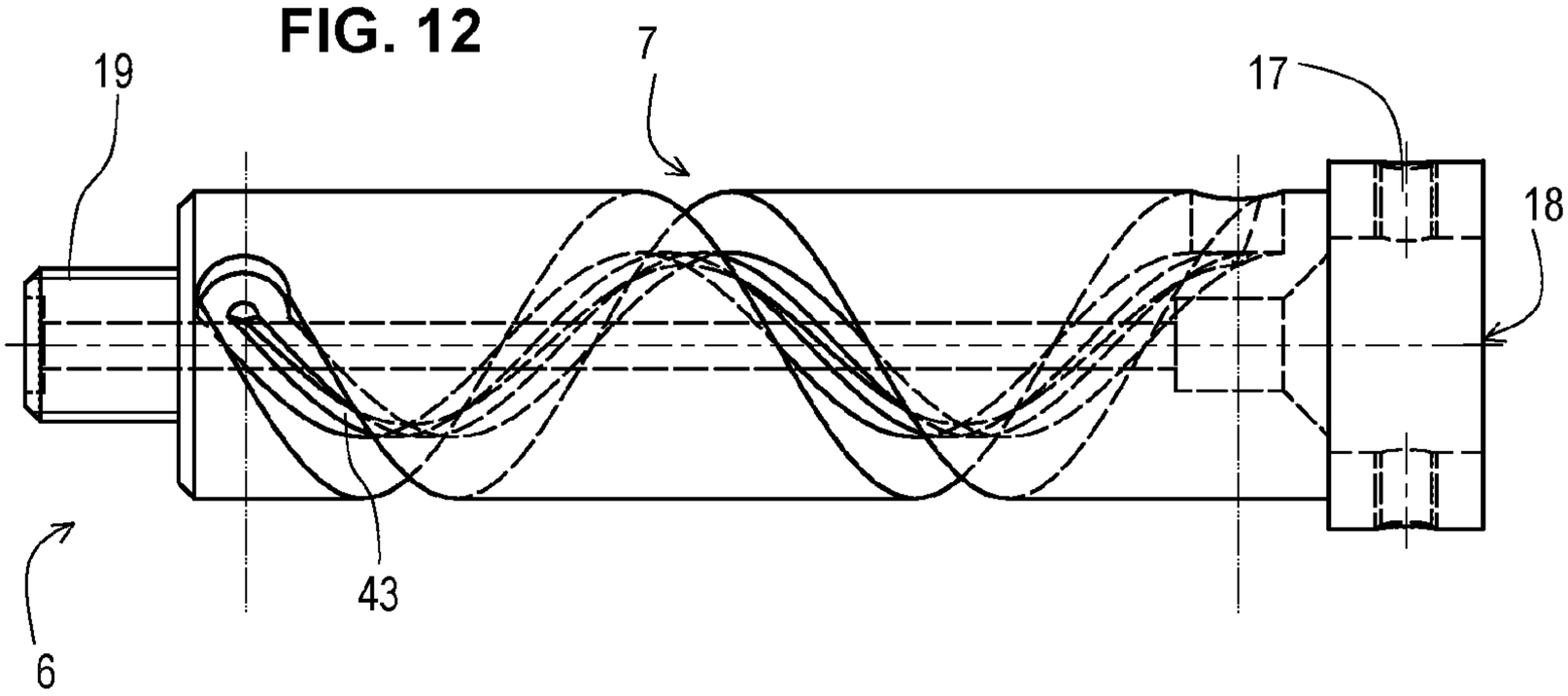


FIG. 12

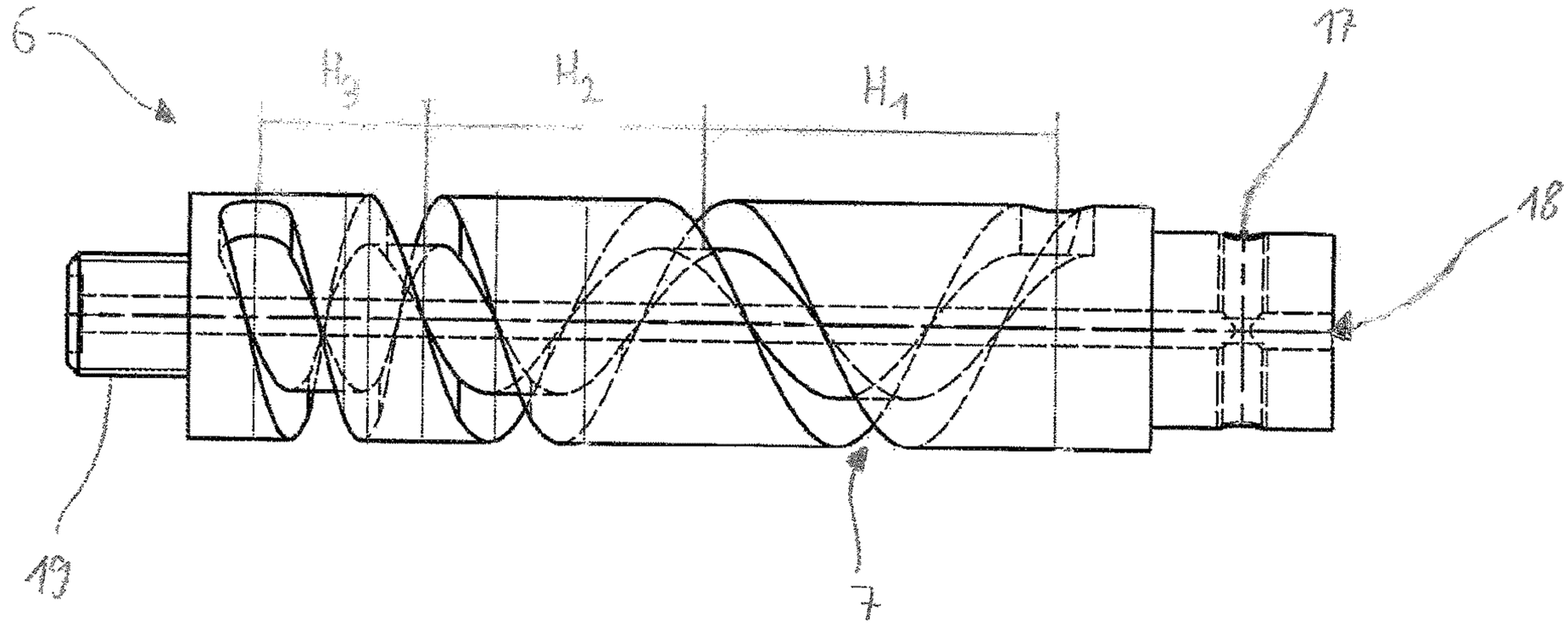


FIG. 13

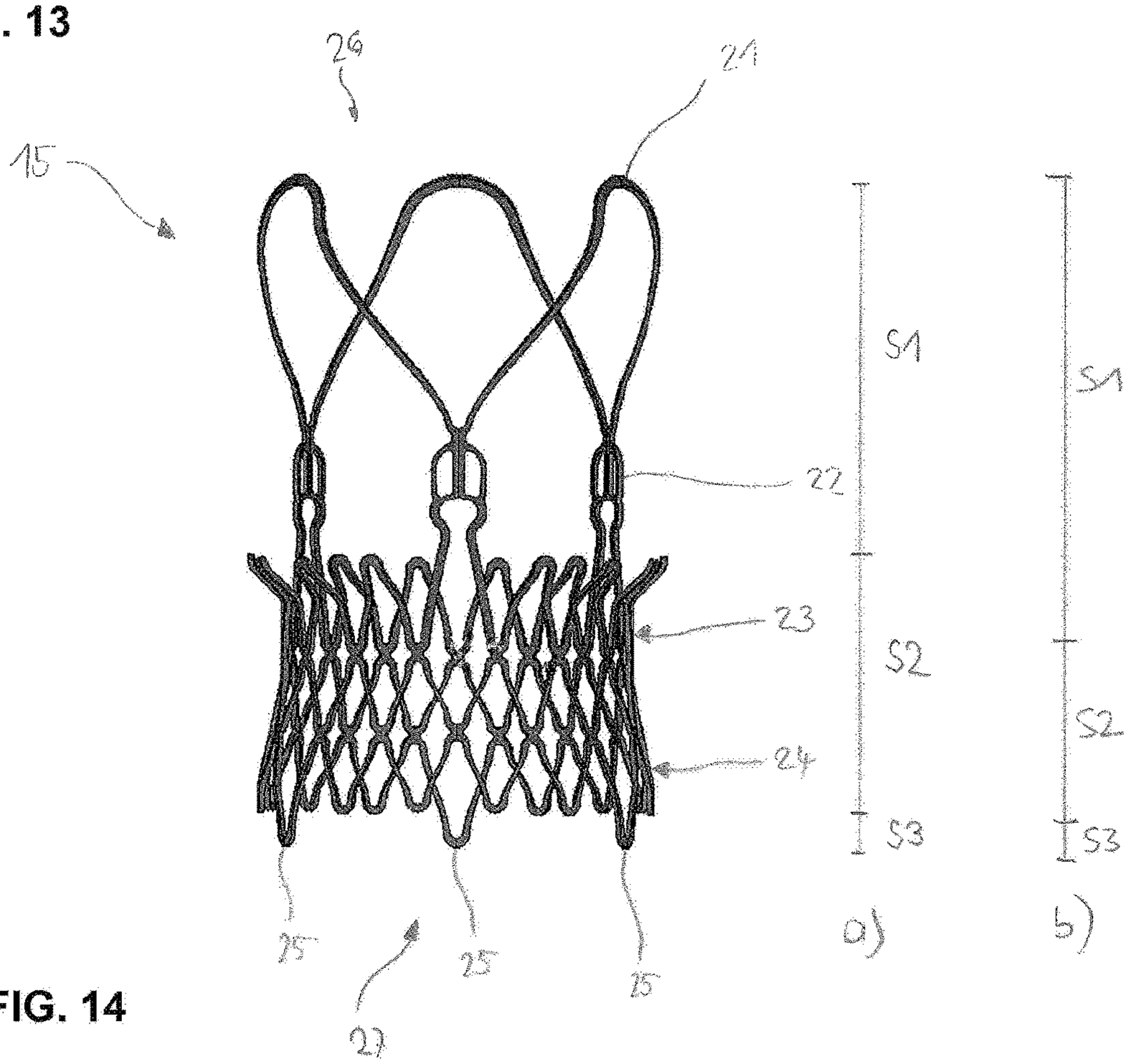


FIG. 14

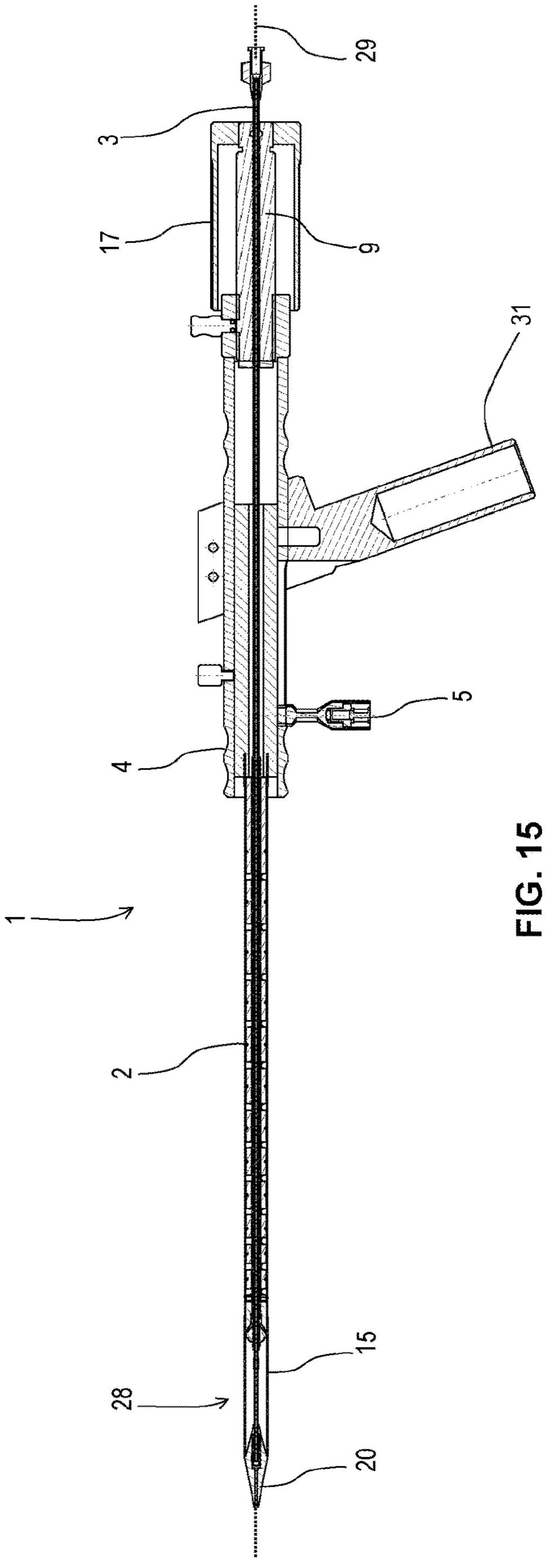


FIG. 15

CATHETER DELIVERY SYSTEM FOR STENT VALVE

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation of U.S. application Ser. No. 15/588,498, filed May 5, 2019, which is a continuation of U.S. application Ser. No. 13/821,434, filed May 20, 2013, now U.S. Pat. No. 9,675,485, which in turn is a national stage entry of PCT Application No. PCT/EP2011/065620, filed Sep. 9, 2011, which claims priority to European Patent Application No. 10176263.1, filed Sep. 10, 2010, and U.S. Application No. 61/431,333, filed Jan. 10, 2011. The present application incorporates herein by reference the disclosures of each of the above-referenced applications in their entireties.

FIELD OF THE INVENTION

The present invention relates to catheter delivery systems for stent valves according to the independent claims.

BACKGROUND TO THE INVENTION

Conventional approaches for cardiac valve replacement require the cutting of a relatively large opening in the patient's sternum ("sternotomy") or thoracic cavity ("thoracotomy") in order to allow the surgeon to access the patient's heart. Additionally, these approaches require arrest of the patient's heart and a cardiopulmonary bypass (i.e., use of a heart-lung bypass machine to oxygenate and circulate the patient's blood). In recent years, efforts have been made to establish a less invasive transcatheter cardiac valve replacement procedure, via either a transvascular approach, i.e. delivering the new valve through the femoral artery, or by transapical route, where the replacement valve is delivered between ribs and directly through the wall of the heart to the implantation site.

Valve stents for use within a human body usually comprise a valve component and a stent component. The stent component is configured to house at least a portion of the valve component. According to some known proposals (see e.g. WO 2009/053497), the stent component further includes a lower anchoring crown comprising an at least partly conical body, the lower anchoring crown defining the proximal end of the stent component. The stent component further comprises an upper anchoring crown in communication with the lower anchoring crown and comprising an at least partly conical body, whereby the conical body of the lower anchoring crown slopes outwardly in the direction of the proximal end, and the conical body of the upper anchoring crown slopes outwardly in the direction of the distal end. A conical or cylindrical commissural post section is located distally of the distal end of the upper anchoring crown. Further distally, a stabilization arch section is comprised.

While less invasive and arguably less complicated, percutaneous heart valve replacement therapies (PHVT) still have various shortcomings, including ease of use of a delivery system for the replacement valve, which can directly influence the inability for a surgeon to ensure proper positioning and stability of the replacement valve within the patient's body. Specifically, if the replacement valve is not placed in the proper position relative to the implantation site, it can lead to poor functioning of the valve. For example, in an aortic valve replacement, if the replacement valve is placed too high, it can lead to valve regurgitation, instability, valve prolapse and/or coronary occlusion. If the valve is placed too low, it can also lead to regurgitation and mitral valve interaction.

SUMMARY OF THE INVENTION

It may be desirable to provide a catheter delivery device for stent valves avoiding the shortcoming known in the art and specifically to provide a delivery catheter system allowing for a simple and effective use, to facilitate accurate positioning and deployment of a stent valve. Some of the following description refers generally to a stent while some embodiments illustrate a stent in the form of a stent-valve. References to a stent may be read optionally as referring to a stent-valve, and vice-versa.

Broadly speaking, one aspect of the invention provides a delivery catheter for a stent. The delivery catheter may comprise a distal end and a proximal end. The distal end includes a stent attachment region adapted to receive a stent. The stent may be of the self-expanding type. The catheter further comprises a handle (also referred to as handle portion) at its proximal end and at least one sheath which may at least partially circumferentially cover said stent such as to retain it in a collapsed configuration. The sheath is coupled at its proximal end to an actuator located on said handle portion. The delivery catheter may further comprise one, or any combination of two or more, of the following features (which are all optional):

(i) The actuator may comprise a manual rotary control (also referred to herein as a rotary handle part) arranged such as to move the sheath in the distal and/or proximal direction (s) in response to rotation thereof. The actuator may comprise a single rotary control. Optionally, the rotary control is coaxial with, and/or configured to rotate around, a longitudinal axis of the catheter.

In some embodiments, the single rotary control is configured to drive translation (e.g. linear translation) of the sheath over a full operative range of movement of the sheath.

In some embodiments, the actuator is configured to drive translation of the sheath from a (e.g. fully) closed position to a (e.g. fully) open position by three complete turns or less of the rotary control, optionally two complete turns or less (measured in quarter turns, e.g., ¼ turn, ½ turn, complete turn, etc.). The translation of the sheath may be at least 50 mm, or at least 60 mm, or at least 70 mm. Such a relatively large translation of the sheath for relatively few turns of the rotary control may involve a relatively coarse thread pitch of a threaded element for converting the rotary movement into linear translational movement. The delivery catheter may optionally comprise a friction member for resisting rotation of the rotary control. The friction member may comprise a protuberance or member carried on at least one of confronting surfaces of a handle housing and the rotary control. For example, the friction member may be provided on an outer surface of the handle housing, and/or an inner surface of the rotary control. Such positioning can provide a relatively large friction-generating contact area, facilitate ease of construction and provide predictable control of the amount of friction generated. In some embodiments, the friction member comprises an O-ring, for example, of elastomeric material.

In some embodiments, the rotary control has an elongate shape (e.g. its axial length is longer than its diameter, for example at least twice as large).

In some embodiments, the rotary control has an axial length of at least 3 cm, or at least 4 cm, or at least 5 cm, or

at least 6 cm, or at least 7 cm, or at least 8 cm, or at least 9 cm, or at least 10 cm. Such sizes can facilitate intuitive gripping in the hand, for example, cupping the rotary control with the fingers and/or palm. The outer shape of the rotary control may be generally cylindrical and/or generally drum-like.

(ii) The rotary control may be configured to translate linearly with respect to a handle housing as the rotary control is rotated. Such translation progressively exposes indicia on the housing and/or control, the indicia indicating an extent of displacement of the sheath at the distal end. Such an arrangement provides an operator with an important indication of the state of the distal end of the delivery catheter. A surgeon may use this indication (optionally in combination with live-imaging of the implantation site, such as live x-ray imaging) to better monitor and control the stent implantation procedure.

In some embodiments, the rotary control may translate linearly in unison with translation of the sheath. The indicia may be a full-scale (e.g. life size) representation of the position or state of the sheath at the distal end.

In some embodiments, indicia on the handle are repeated, to be presented at least two different positions around the circumference of the handle, or at least three such different positions, or at least four different such positions. This may permit the indicia to be easily visible independently of a rotational orientation of the handle. Alternatively, the indicia may comprise one or more annular closed and/or split ring-shaped markings visible from substantially any orientation of the handle.

(iii) Additionally or alternatively, the stent carried by the delivery catheter comprises a first portion and a second portion intended to be deployed in respective first and second distinct deployment phases. For example, the first and second portions may be intended to fit on opposite sides of the annulus of an existing (e.g., native) valve. The first portion may be supra-annular and the second portion may be sub-annular. Additionally or alternatively, the first and second portions may comprise opposed crowns and/or oppositely divergent portions.

In some embodiments, the handle of the delivery catheter comprises indicia associated with movement of the actuator, for indicating at least one limit position associated the first and/or second deployment phases. A surgeon may use this indication (optionally in combination with live-imaging of the implantation site, such as live x-ray imaging) better to monitor and control the stent implantation procedure. In particular, the surgeon may, by checking the indicia, know how close the delivery catheter is to reaching the end of a respective deployment phase. Such information may be less evident from live imaging alone. This may enable the surgeon better to adapt the speed of deployment.

In some embodiments, indicia on the handle are repeated, to be presented at least two different positions around the circumference of the handle, or at least three such different positions, or at least four different such positions. This may permit the indicia to be easily visible independently of a rotational orientation of the handle. Alternatively, the indicia may comprise one or more annular closed and/or split ring-shaped markings visible from substantially any orientation of the handle.

(iv) The handle may have a profile including a bulbous, e.g rounded, portion providing a tactile positioning guide for an operator's hand. The handle may optionally comprise a single bulbous portion.

The rounded bulbous portion may have a radial height, compared to at least one adjacent surface of the handle, of at least 5 mm, at least 6 mm, at least 7 mm, or at least 8 mm. The rounded bulbous portion may have an axial extent of any of: at least 20 mm; at least 25 mm; at least 30 mm. Additionally or alternatively to any of the above, the rounded bulbous portion may have an axial extent of: not greater than 40 mm; not greater than 30 mm; not greater than 35 mm.

The rounded portion may have a part-spherical and/or frusto-spherical shape. The rounded portion may have a radius of curvature of any of: at least 15 mm; at least 20 mm; at least 23 mm. Additionally or alternatively to any of the above, the radius of curvature may optionally be: not greater than 60 mm; not greater than 50 mm; not greater than 40 mm; not greater than 30 mm; not greater than 25 mm; not greater than 23 mm.

Such arrangements can provide a highly intuitive and versatile tactile positioning guide for the handle. The guide may fit snugly in the palm of the hand, and/or be cupped comfortably by the fingers. The guide may also provide a suitable surface for gripping with the fingers to apply axial force to the handle. The guide may also provide substantially the same feel to the operator whatever the rotational orientation of the handle around the catheter axis.

In some embodiments, the actuator may be distinct from the rounded bulbous portion.

The rounded bulbous portion may be an integral part of the handle and/or a housing forming at least a portion of the handle.

(v) In some embodiments, the handle may be generally radially symmetrical. For example, the handle may be absent any cantilever handle grips. This may enable the delivery catheter to be versatile for use with any rotational orientation about the catheter axis, without the orientation making the handle more awkward to hold, manipulate or observe. This may be especially advantageous where the stent has a non-predetermined rotational orientation with respect to the delivery catheter and/or where the delivery catheter may need to be rotated about its longitudinal axis for aligning the stent with respect to the native anatomy. For example, the handle may have a generally round cross-section profile.

In some embodiments, indicia on the handle are repeated, to be presented at least two different positions around the circumference of the handle, or at least three such different positions, or at least four different such positions. This may permit the indicia to be easily visible independently of a rotational orientation of the handle. Alternatively, the indicia may comprise one or more annular closed and/or split ring-shaped markings visible from substantially any orientation of the handle.

(vi) The handle may further comprise at least one indicator rotatable about a catheter axis. The indicator may be positionable to indicate a rotational alignment of a stent (e.g., stent-valve) with respect to the handle. The indicator may be manually positionable.

This aspect of the invention may enable the operator to set a convenient indication of the rotational alignment of the stent. In some embodiments, the rotational orientation of the stent may be variable or non-predetermined with respect to the delivery catheter. For example, the stent may have a variable or non-predetermined orientation with respect to a stent holder of the attachment region. Additionally or alternatively, the stent holder may have a non-predetermined orientation with respect to the handle. However, although the orientation may be non-predetermined, it may be unlikely to change after loading of the stent into the delivery catheter. The orientation may be visible during and/or following loading, allowing the indicator to be set accordingly

to provide an indication useful for the implantation procedure. Once the distal end has been inserted into the body, the distal end (and the stent) is no longer directly visible. The operator may have access to live imaging (e.g. x-ray imaging) from which the rotational orientation may be deduced. However, the provision of an indicator directly at the handle can provide a direct and intuitive indication of the orientation to further assist the operator, and remove any ambiguity from the x-ray imaging.

In some embodiments, the stent is a valve stent (also referred to as a stent-valve) comprising a valve having valve leaflets meeting at, and/or supported at, a plurality of peripheral commissures. The indicator may comprise indicia for indicating the rotational orientation of the commissures. The indicator may comprise plural indicia, e.g. one for each commissure.

The indicator may comprise a rotatable collar mounted towards a distal end of the handle. The rotatable collar may bear indicia (e.g. laser inscribed indicia, or indicia members embedded at least partly within the collar).

(vii) The delivery catheter may further comprise a stem portion extending between the handle and the distal portion. The stem portion may have a flexure characteristic such that, in order to produce flexure displacement of 10 mm using a three-point bending test, the applied force is between 2.5 and 7.5 N (inclusive range). The three-point bending test may comprise supporting the stem portion at two spaced apart positions, and observing the degree of bending displacement (e.g., with respect to a straight axis) when a force is applied, in a diametrically opposed direction to the supports, at a position midway between the spaced apart support positions. The test may be carried out at room temperature.

Optionally, the defined range of applied force may be associated with a spacing between the supports that is between about 16 and about 20 times the outer diameter of the stem.

In one example, the spacing between the supports may be 20 times the outer diameter of the stem. The applied force may be between 2.5 and 4.5 N. Optionally the applied force may be at least 2.6N, optionally at least 2.7N, optionally at least 2.8N, optionally at least 2.9N, optionally at least 3.0N, optionally at least 3.1N, optionally at least 3.2N, optionally at least 3.3N, optionally at least 3.4N, optionally at least 3.5N, optionally at least 3.6N, optionally at least 3.7N, optionally at least 3.8N, optionally at least 3.9N, optionally at least 4.0N. Additionally or alternatively to any of the above, the applied force may optionally be no greater than 4.0N, optionally no greater than 3.9N, optionally no greater than 3.8N, optionally no greater than 3.7N, optionally no greater than 3.6N, optionally no greater than 3.5N, optionally no greater than 3.4N, optionally no greater than 3.3N, optionally no greater than 3.2N, optionally no greater than 3.1N. Optionally, the applied force may be between about 3.0N and about 3.7N

In another example, it may not be practical to using a spacing of 20 times the outer diameter of the stem if (for example), the stem as used in the delivery device is shorter than would be needed for such measurement. For example, the outer diameter may be about 9.8 mm (+−0.5 mm), and the available length for measurement may be about 160 mm. In that case, the ratio of the distance (spacing) divided by the outer diameter is about 16. For such an example (spacing 160 mm and/or outer diameter of 9.8 mm (+−0.5 mm) and/or a spacing of about 16 times the outer diameter, the applied force may be between about 6.0 and about 7.5N. Optionally, the applied force may be at least 6.1N, optionally at least 6.2N, optionally at least 6.3N, optionally at least 6.4N, optionally at least 6.5N, optionally at least 6.6N, optionally at least 6.7N, optionally at least 6.8N, optionally at least 6.9N, optionally at least 7.0N, optionally at least 7.1 N, optionally at least 7.2N, optionally at least 7.3N, optionally at least 7.4N. Additionally or alternatively to any of the above, the applied force may optionally be no greater than 7.4N, optionally no greater than 7.3N, optionally no greater than 7.2N, optionally no greater than 7.1N, optionally no greater than 7.0N, optionally no greater than 6.9N, optionally no greater than 6.8N, optionally no greater than 6.7N, optionally no greater than 6.6N, optionally no greater than 6.5N, optionally no greater than 6.4N, optionally no greater than 6.3N, optionally no greater than 6.2N, optionally no greater than 6.1 N. Optionally, the applied force may be between about 6.5 and about 7.0N

Such flexure characteristics may be advantageous in meeting the conflicting desirata of flexibility and support. Especially in the case of a transapical approach, the delivery catheter has to provide sufficient support to be able to advance the distal end through a relatively tight access aperture in the ventricle wall. It is desirable that the aperture in the ventricle be as small as possible, to reduce risk of interference with the distribution of natural electrical pulses essential to healthy heart operation, and/or reduce the invasiveness of the procedure on the heart tissue, and/or facilitate easier closing after the procedure to restore the integrity of the ventricle wall, and/or facilitate the patient's recovery after the procedure. It is desirable to create the access aperture undersized, and rely on the elasticity of the heart muscle tissue to allow the aperture to expand elastically to accommodate passage of the delivery catheter therethrough. Such a tight fit can also provide a self-seal against blood leakage, the procedure being carried out while the heart remains beating to pump blood around the circulatory system. However, the delivery catheter has to support application of force from the proximal end to drive the distal portion through such an undersized aperture. The delivery catheter also has to be flexible to accommodate a non-straight delivery path through the heart and the existing valve. Additionally, different surgeons have different preferences for the entry path through the anatomy to the heart. For example some surgeons prefer a relatively flat entry along a direction close to the patients body, while others prefer a more inclined path. A stiff catheter can provide excellent support, but without flexibility the catheter may not accommodate the non-straight delivery path, but may be difficult to introduce and position, and may not achieve optimum positioning of the prosthetic valve. The flexure characteristic defined herein can provide a surprisingly good balance between the two.

The three point bending test parameter as defined above is used because, in the some embodiments, the stem portion comprises plural tubes nested one within the other, with or without a substantial clearance therebetween. A small flexure might only involve flexing of one tube. The above parameter can provide a consistent parameter applicable to the entire stem portion instead of only a single tube.

(viii) In some embodiments, the distal end is intended to be inserted into a human body, such as into the heart and/or circulatory system. The proximal end is intended to stay outside of the patient and to allow manipulation of the catheter by an operator, e.g. a surgeon. The distal and the proximal end are thereby connected by a stem or trunk portion, comprising at least one tubular member.

As understood herein, the terms "distal" and "proximal" define the orientation of an element from the operator of the

delivery device. Therefore, the "proximal end" is the end of the catheter device which is nearer to the operator, while the "distal end" is farther away.

At the distal end, the catheter delivery system includes a stent attachment region. In some embodiments, the stent attachment region comprises retaining means such as to retain the stent on the catheter at a defined longitudinal position. This allows the user to advance the catheter through a portion of the heart of a patient, e.g. through a ventricle, or through the vasculature of a patient, e.g. through the aorta, without the danger that the stent might slip off the catheter. In some embodiments, the retaining means are thereby configured in such a way as to release the stent during or just after its expansion.

The stent used in connection with the catheter delivery system according to the present invention may be of the self-expanding type. Such stents are known in the art and are made of or comprise a superelastic material such as a Nickel-Titanium alloy, e.g. available under the name Nitinol. Alternatively the stent might also be made of or comprise other metallic materials, such as metallic materials exhibiting some elasticity. Further alternatively, the stent might also be deployable by means of a balloon or the like.

The catheter delivery device further comprises a handle portion located at its proximal end. The handle portion provides means for an operator to hold and operate the catheter delivery system. These may include handles, knobs, buttons, trigger elements, etc.

Further, the delivery device comprises at least one sheath. Said sheath may at least partially circumferentially cover the stent. By covering the stent, the sheath holds the stent in a collapsed configuration, such that the stent may be introduced into the circulatory system. In some embodiments, the sheath completely covers the stent during insertion. Once the stent is positioned at the right place, e.g. over the aortic valve, the sheath may be moved proximally over the stent, thereby sequentially uncovering the stent. The portions of the stent which are uncovered are thereby free to expand.

For this purpose, the sheath is coupled to an actuator located on said handle. The coupling thereby is either direct or indirect, depending on the kind of actuator used. Especially in the case where the actuator comprises a rotational movement, an element transforming said rotational movement into a translational movement may be arranged between the sheath and the actuator. The element may, for example, be threaded. The thread may be helical.

In some embodiments, the actuator in the catheter delivery system according to the present invention consists of a single rotary handle or handle part. This handle (part) is thereby arranged in such a way as to move the sheath either in the distal or in the proximal direction. In some embodiments, the rotary handle (part) is configured in such a way as to move the sheath both in the distal and in the proximal direction, for example, depending on the direction of rotation of the actuator. This offers the advantage that the sheath may not only be moved over the stent along the proximal direction thereby releasing the stent, but also along the distal direction thereby re-capturing the stent and/or facilitating loading of the stent into the delivery catheter. In some embodiments, it may be possible to revert certain expanded portions of the stent into the collapsed configuration. This may allow repositioning of a stent if needed.

The rotary handle (part) may be configured in any suitable way. In some embodiments, the rotary handle (part) is in the form of a cylinder arranged at the proximal end of the handle. Alternatively, the rotary handle may also be configured as knob or crank.

(ix) The delivery catheter includes gear means providing for at least two different transmission or gear ratios between the movement of actuation means and the movement of the sheath, depending on the position of the distal end of the sheath along the stent and/or with respect to the attachment region.

The gear means allow for at least two different gear ratios between the movement of the actuation means and the movement of the sheath. The gear ratio thereby is the proportion between the distance that the distal end of the sheath is moved in comparison to the distance that the actuation means has been moved. For example, in the case of a rotary handle, a constant gear ratio would mean that for every turn of the handle the distal end of the sheath would move along the same distance. As soon as a gear means with at least two different gear ratios depending on the position of the distal end of the sheath along the stent is used, the distal end of the sheath moves a certain first distance for every turn of the handle with the first gear ratio and a second distance different from the first distance for every turn of the handle with the second gear ratio. The second distance may be bigger or smaller than the first distance.

A low gear ratio means that the distal end of the sheath will move a shorter distance along the stent compared to the movement of the actuation means. Taking a rotary handle as an example, this means that the distance which the distal end of the sheath moves for every turn of the handle will be shorter than with a higher gear ratio.

Such a configuration allows providing a catheter delivery system having different unsheathing characteristics depending on which portion the distal end of the sheath is being moved. Specifically, the delivery device can be configured such that a small gearing ratio is provided when the distal end of the sheath is moving along portions of the stent requiring slower and/or more accurate deployment.

The gear means also provides a kind of feedback mechanism to the operator. The force needed to move the sheath will be higher with a high gear ratio compared to a low gear ratio. In the case of a rotary handle, this translates into a higher torque to be applied to the handle. This can readily be sensed by an operator or alternatively be measured by an instrument.

In some embodiments, the catheter delivery device according to the present invention comprises a single rotary handle as actuation means, whereby said rotary handle is arranged such as to move the sheath both in the distal and the proximal direction, wherein a gear means is arranged between said rotary handle and the proximal end of said sheath.

Alternatively, the actuation means may also comprise a trigger element moveable in the distal and the proximal direction. The trigger element is thereby configured such as to move the sheath element in the distal and/or the proximal direction, wherein a gear means is arranged between the proximal end of the sheath and the trigger element.

In some embodiments, said gear means is configured such that when the sheath is moved in the proximal direction to unsheath the stent, the gearing means provides a different gear ratio, such as a higher gear ratio when the sheath moves along a first portion of the stent compared to the gear ratio provided when it moves along a second portion of the stent located proximally to said first portion.

When used in combination with a valve stent intended for trans-apical insertion, this means that unsheathing and hence deployment of the distal part of the stent located in the aorta will take place with a high gear ratio. Especially but not exclusively in the case that the most distal parts usually do

not serve to anchor the stent but rather comprise stabilizing means, the operator needs a less precise control of the deployment. Further, a high gear ratio enables a quicker deployment as compared with a lower gear ratio. The more proximal portions of the stent may comprise one or more anchoring crowns. Especially but not exclusively in the case that it is important to have a correct placement and orientation of the stent when deploying the anchoring crown or crowns, it is advantageous to use a low gear ratio, as this enables the operator to have a more accurate control on the deployment. Further, the deployment speed will also be lower, thereby reducing the risk of miss orientation of the crown. As the force needed to move the sheath is also lower when using a lower gear ratio, re-capture of the stent may be easier.

In some embodiments, said gear means is further configured such that the gear ratio provided when the sheath moves along said second portion of the stent is different (e.g., lower), compared to the gear ratio provided when the sheath moves along a third portion of the stent located proximally to said second portion.

In some embodiments, the most proximal portion of the stent comprises attachment elements adapted to be coupled to the retaining means located on the catheter. The coupling may be configured in such a way as to provide for a de-coupling of the stent as soon as its most proximal portion expands. This may e.g. be achieved by providing loops on the most proximal portion of the stent which are mounted on pins provided on the catheter. As long as the stent is held in its collapsed configuration, the pins remain within the loops, thereby realisably coupling the stent to the catheter. As soon as the stent expands, the loops will slip over the pins thereby uncoupling the stent from the catheter. Alternatively, any other suitable coupling means may be used.

As it is favourable that all coupling means are decoupled simultaneously such as to not lead to a miss orientation of the stent, it is desirable that the distal end of the sheath may be moved quicker along the most proximal portion of the stent than along the foregoing portions. This is achieved by providing a higher gear ratio.

In some embodiments, the gear means comprises a cylindrical threaded element having at least two regions with a different thread pitch.

The thread pitch is the distance along the longitudinal axis between two crests of the thread. As the threaded element according to the present invention has a single thread, the pitch corresponds to the lead. Therefore the pitch may also be defined as the advancement of the sheath for each turn of the threaded element.

Providing a gear means with a cylindrical threaded element provides for a simple and easy to use catheter delivery device. In one embodiment, the cylindrical threaded element may be provided within the handle and may be directly coupled to the actuation means provided as rotary handle. On the inside of the handle, a pin may be provided which engages the thread. In an alternative embodiment, the thread may be provided on the inner side of a rotary actuation means provided as hollow cylinder. The sheath is thereby coupled to a pin which engages the thread. Further, any other suitable configuration may be used.

The thread may be provided with any suitable profile. In some embodiments, the thread has a rectangular or rounded profile. Alternatively, the thread may also comprise a triangular profile.

The pin which is engaged into the thread may comprise a rolling ball at its tip, thereby reducing the friction force between the pin and the thread.

The threaded element comprises a thread with a greater pitch in a first region compared to the pitch in a second region, said greater pitch allowing a greater gear ratio when the sheath moves along the first portion than along the second portion of the stent.

In a further embodiment, the threaded element comprises a thread with a greater pitch in a third region compared to the pitch in the second region, said greater pitch allowing a greater gear ratio when the sheath moves along the third portion of the stent than over the second portion.

This allows providing a catheter delivery system with a gear means comprising different gear ratios.

Further, alternatively, the gear means is configured such that different gear ratios are provided when the sheath moves along the second portion of the stent, such as by providing a varying pitch on the second region of the threaded element.

This provides for different sensitivities and/or unsheathing speeds when deploying the central portions of a stent. E.g. the gear ratio may be varied for deployment of the upper and/or the lower crown of the stent.

In some embodiments, the cylindrical threaded element is exchangeable. As such, it is possible to easily vary the combination of gear ratios, and especially to provide specific combinations for different stent application methods and/or stent sizes.

(x) The catheter comprises feedback or braking means (e.g., tactile feedback means) to indicate when the distal end of the sheath has reached a defined position on the stent during proximal and/or distal movement of said sheath along said stent or to cause a braking effect when the distal end of the sheath has moved beyond a certain position along the stent.

The feedback means may be tactile means. This allows the operator to sense when the distal end of the sheath has reached a defined position. As the feedback means have a direct influence on the movement the operator uses to deploy the stent, the feedback will be more direct than if other feedback means, such a light or sound signal were used. Advantageously, the feedback means warn the operator that the distal end of the sheath is about to move over the proximal end of the stent.

Alternatively, a catheter delivery device according to the present invention may comprise more than one feedback and/or braking means, such as two, three or more defining various predetermined intermediate positions.

In one embodiment, said feedback means comprise at least one removable pin or stop limiting the movement of said distal end of the sheath beyond a certain position on the stent. Once the distal end of the sheath reaches the defined position, no further movement will be possible until the stop is removed. Alternatively, an element may be provided which does not completely stop the movement, but which may be pushed out, e.g., against the force of a spring. As the removal of the pin or stop by moving the actuation means further will require some additional force, the operator will have a tactile feedback.

In an alternative embodiment, the feedback means may be formed as a braking means comprising an element applying an additional resistance to the actuation means once the distal end of the sheath moves beyond a certain point on the stent. This may be achieved by means of additional friction forces acting on the actuation means or the sheath. The resistance may alternatively also be applied by a gear means.

Further, alternatively, the feedback or braking means may comprise a threaded element with a varying thread pitch, wherein a decrease of said thread pitch increases the resistance of the actuation means. Such a feedback or braking

means is especially advantageous on catheter delivery devices where the actuation means consist of a trigger element.

Said feedback means may be arranged such as to avoid movement of the sheath beyond a position on said stent beyond which an increased risk of unwanted self-deployment of the stent exists.

Once the distal end of the sheath is near the proximal end of the stent, there is a certain risk that the stent pushes itself out of the sheath by means of the expansion force. This may lead to an unwanted release of the stent before it is correctly oriented and placed. To avoid such a premature release, the movement of the distal end of the sheath beyond a certain point where this risk exists may be stopped or slowed down by the feedback or braking means.

Broadly speaking, a further independent aspect of the invention relates to a stop that is removably engageable with a delivery catheter for blocking or resisting deployment movement of a portion of the catheter for deploying a stent therefrom, at least beyond a predetermined deployment position. The deliver catheter may optionally include any of the aforementioned features. The removable stop may comprise first and second parts movable relative to each other.

The removable stop may optionally further comprise any one or any combination of two or more of the following features (which are all optional):

(i) The first and second parts may be arranged one part for bearing a removal force, and the other part for bearing at least a portion of an opposite reaction to the removal force.

Such a stop is highly advantageous by reducing, to a large extent, the reaction to the removal force applied to the delivery device itself. For example, if using a traditional pull-out friction-fit pin, the surgeon has to support the delivery device with one hand in order to support the reaction to the force applied with the other hand to pull-out the pin. Similarly, if using a screw threaded pin, the surgeon has to support the delivery device with one hand to support the reaction to the unscrewing force applied with the other hand to the pin. Unscrewing may also be inconvenient during an implantation procedure. In both cases, the reaction to the removal force is applied to the delivery device, and there is a risk that minor movements of the delivery catheter handle when transmitted to the stent at the distal end, may have undesirable effects. For example, the stent may be partly deployed and/or be in operative contact with the anatomy. Minor movement can sometimes cause accidental release of the stent or displace the stent out of a desired implantation position. In contrast, with the present aspect of the invention, the two-part configuration of the removable stop can reduce significantly the reaction to the removal force experienced by the delivery catheter.

The first and second parts may be substantially coaxial about an axis of the stop, and slidable relative to each other along said axis.

One of the first and second parts of the stop may comprise a pull-out friction-fit within an aperture of the delivery catheter handle, and the other part may comprise a pusher for pushing against the delivery device.

(ii) The first and second parts may have spaced apart portions that, when squeezed one towards the other, are configured to release the stop from the handle.

A further independent aspect of the invention provides a method of using a delivery catheter for implanting a stented prosthetic aortic valve, the delivery catheter having a distal portion comprising: a tip member and a sheath movable with respect to the tip member, the distal portion carrying the prosthetic aortic valve constrained by the sheath, the sheath having a closed position in which the sheath abuts the tip member; the method comprising: (a) advancing the distal portion within a patient's anatomy towards the implantation site; (b) subsequently partly displacing the sheath with respect to the tip member such that the sheath is spaced from the tip member, without deploying substantially the stent; (c) subsequently further advancing the distal portion with the sheath spaced from the tip member, the spacing permitting the tip member to flex with respect to the sheath member; (d) subsequently further displacing the sheath with respect to the tip member in order to deploy the stent.

Such a method can address an issue of the sheath, when abutting the tip member, potentially limiting the freedom of the tip member to flex. By partly displacing the sheath from the tip member, at least after having penetrated the heart and/or vascular system, the tip member can be allowed more freedom to flex at the expense of reduced support. This can be used to assist advancement of the distal portion without deploying the stent. For example, for a transapical delivery catheter, by partly displacing the sheath from the tip member after having penetrated the ventricle (such as after having passed through an existing valve), the tip member can be allowed more freedom to flex. This can assist introduction and/or advancement of the distal portion in the ascending aorta and/or in the aortic arch, especially in cases where a person's individual anatomy may make such advancement difficult.

According to some embodiments, a delivery catheter for a stent is provided wherein the delivery catheter comprises a distal end and a proximal end, the distal end including a stent attachment region adapted to receive a stent, the catheter further comprising a handle at its proximal end and at least one sheath for at least partially circumferentially covering said stent such as to retain it in a collapsed configuration, the sheath being coupled at its proximal end to an actuator located on said handle for actuating movement of the sheath, the handle further comprising an indicator rotatable about the longitudinal axis of the catheter, the indicator being positionable to indicate a rotational orientation of a stent with respect to the handle. The delivery catheter of some embodiments may comprise an indicator that is manually settable. The stent may be a valve stent comprising a valve having valve leaflets and associated peripheral commissures, and wherein the indicator comprises indicia for indicating the rotational orientation of at least one of the commissures.

According to some embodiments, a delivery catheter for a stent is provided wherein the delivery catheter comprises a distal end and a proximal end, the distal end including a stent attachment region adapted to receive a stent, the catheter further comprising a handle at its proximal end and at least one sheath for at least partially circumferentially covering said stent such as to retain it in a collapsed configuration, the sheath being coupled at its proximal end to an actuator located on said handle for actuating movement of the sheath, wherein the handle comprises a bulbous portion intermediate distal and proximal ends of the handle, the bulbous portion providing a tactile positioning guide for an operator's hand.

The bulbous portion may be one or more selected from: (i) rounded; (ii) frusto-spherical; (iii) distinct from the actuator. The bulbous portion may have one or more dimensions selected from: (i) a radial height compared to at least one adjacent surface of at least 5 mm; (ii) an axial extent of at least 20 mm; (iii) a radius of curvature of at least 15 mm; (iv) a radius of curvature not greater than 60 mm.

According to some embodiments, a delivery catheter for a stent is provided wherein the delivery catheter comprises a distal end and a proximal end, the distal end including a stent attachment region adapted to receive a stent, the catheter further comprising a handle at its proximal end and at least one sheath for at least partially circumferentially covering said stent such as to retain it in a collapsed configuration, the sheath being coupled at its proximal end to an actuator located on said handle for actuating movement of the sheath, the actuator comprising a manual rotary control arranged such as to move the sheath in the distal and/or proximal direction(s) along an operative range of movement in response to rotation of the rotary control through three turns or less around the longitudinal axis of the catheter. The delivery catheter may further comprise a friction member for frictionally resisting rotation of the rotary control.

According to some embodiments, a delivery catheter for a stent is provided wherein the delivery catheter comprises a distal end and a proximal end, the distal end including a stent attachment region adapted to receive a stent, the catheter further comprising a handle at its proximal end and at least one sheath for at least partially circumferentially covering said stent such as to retain it in a collapsed configuration, the sheath being coupled at its proximal end to an actuator located on said handle for actuating movement of the sheath, the actuator comprising a manual rotary control rotatable around the longitudinal axis of the catheter and arranged such as to move the sheath in the distal and/or proximal direction(s), the rotary control having a longitudinal length of at least 4 cm. The rotary control may be elongate in the direction of the longitudinal axis of the \\SeagerDC\Company Shared\Final\2001\2001.1856103\20011856103_APP_10-31-2019.docx

According to some embodiments, a delivery catheter for a stent is provided wherein the delivery catheter comprises a distal end and a proximal end, the distal end including a stent attachment region adapted to receive a stent, the catheter further comprising a handle at its proximal end and at least one sheath for at least partially circumferentially covering said stent such as to retain it in a collapsed configuration, the sheath being coupled at its proximal end to an actuator located on said handle for actuating movement of the sheath, the actuator comprising a manual rotary control associated with a helical thread than causes linear translation of the rotary control relative to the handle as the rotary control is turned, the handle further comprising indicia positioned so as to be progressively exposed or covered by the rotary control according to the linear position of the rotary control, the indicia indicating an extent of displacement of the sheath at the proximal portion. The rotary control may be configured such that the linear translation of the rotary control is the same linear translation as the sheath.

According to some embodiments, an assembly is provided comprising a self-expanding stent-valve for replacing an aortic valve, and a delivery catheter of the present invention. The stent may comprise first and second portions configured for engagement, in use, with opposite sides of a native aortic valve annulus. The delivery catheter may comprise a distal end and a proximal end, the distal end including a stent attachment region adapted to receive the stent, the catheter further comprising a handle at its proximal end and at least one sheath for at least partially circumferentially covering said stent such as to retain it in a collapsed configuration, the sheath being coupled at its proximal end to an actuator located on said handle for actuating movement of the sheath, the actuator comprising a manual rotary control, and the handle further comprising indicia for indicating sheath displacement with respect to a first step for deploying the first stent portion and a second step for deploying the second stent portion.

According to some embodiments, a delivery catheter for a stent is provided where the delivery catheter comprises a distal end and a proximal end, the distal end including a stent attachment region adapted to receive a stent, the catheter further comprising a handle at its proximal end and at least one sheath for at least partially circumferentially covering said stent such as to retain it in a collapsed configuration, the sheath being coupled at its proximal end to an actuator located on said handle for actuating movement of the sheath, wherein a stem portion of the delivery catheter extending between said distal and proximal portions has a flexure characteristic such that, in order to produce flexure displacement of 10 mm using a three-point bending test, the applied force is between 2.5 and 7.5 N (inclusive range). The stem portion of the delivery catheter may include a tube member and a sheath member around the tube member.

According to some embodiments, a delivery catheter for a stent is provided wherein the delivery catheter comprising a distal end and a proximal end, the distal end including a stent attachment region adapted to receive a stent, the catheter further comprising a handle at its proximal end and at least one sheath for at least partially circumferentially covering said stent such as to retain it in a collapsed configuration, the sheath being coupled at its proximal end to an actuator located on said handle for actuating movement of the sheath, the delivery catheter further comprising a removable stop for obstructing actuator displacement beyond a certain position, the removable stop comprising first and second parts movable relative to one another, the first and second parts being arranged one part for bearing a removal force, and the other part for bearing at least a portion of an opposite reaction to the removal force.

According to some embodiments, a delivery catheter for a stent is provided comprising a distal end and a proximal end, the distal end including a stent attachment region adapted to receive a stent, the catheter further comprising a handle at its proximal end and at least one sheath for at least partially circumferentially covering said stent such as to retain it in a collapsed configuration, the sheath being coupled at its proximal end to an actuator located on said handle for actuating movement of the sheath, the delivery catheter further comprising a removable stop for obstructing actuator displacement beyond a certain position, the removable stop comprising first and second parts movable relative to one another and having spaced apart portions that, when squeezed one towards the other, are configured to release the stop from the handle.

According to some embodiments, a delivery catheter for delivery of a valve is provided comprising a distal end and a proximal end, said distal end including a stent attachment region adapted to receive a stent, preferably of the self-expanding type; said proximal end comprising a handle; and at least one sheath which may at least partially circumferentially cover said stent such as to retain said stent in a collapsed configuration, said sheath being coupled at its proximal end to actuation means located on said handle, characterized in that said actuation means consists of a single rotary handle part arranged such as to move said sheath in the distal and the proximal direction.

According to some embodiments, a delivery catheter for delivery of a valve stent is provided comprising a distal end and a proximal end, said distal end including a stent attach-

ment region adapted to receive a stent, preferably of the self-expanding type; said proximal end comprising a handle portion; and at least one sheath which may at least partially circumferentially cover said stent such as to retain said stent in a collapsed configuration, characterized in that said delivery catheter further comprises gear means providing for at least two different transmission ratios between the movement of actuation means and the movement of the sheath depending on the position of the distal end of the sheath along said stent.

According to some embodiments, a delivery catheter for delivery of a valve stent is provided comprising a distal end and a proximal end, said distal end including a stent attachment region adapted to receive a stent, preferably of the self-expanding type; said proximal end comprising a handle portion; and at least one sheath which may at least partially circumferentially cover said stent such as to retain said stent in a collapsed configuration, said sheath being coupleable at its proximal end to actuation means located on said handle portion such as to be moved along said stent, characterized in that said catheter further comprises feedback means and/or braking means, preferably tactile feedback means, to indicate when the distal end of the sheath has reached a defined position on the stent during proximal and/or distal movement of said sheath along said stent and/or to cause a braking effect once the distal end of the sheath moves beyond a defined position along the stent.

According to some embodiments, a method is provided for using a delivery catheter for implanting a stented prosthetic aortic valve, the delivery catheter having a distal portion comprising: a tip member and a sheath movable with respect to the tip member, the distal portion carrying the prosthetic aortic valve constrained by the sheath, the sheath having a closed position in which the sheath abuts the tip member; the method comprising: advancing the distal portion within a patient's anatomy towards the implantation site; subsequently partly displacing the sheath with respect to the tip member such that the sheath is spaced from the tip member, without deploying substantially the stent; subsequently further advancing the distal portion with the sheath spaced from the tip member, the spacing permitting the tip member to flex with respect to the sheath member; and subsequently further displacing the sheath with respect to the tip member in order to deploy the stent. The step of advancing may comprise advancing the distal portion along a transapical path. The step of subsequently partly displacing the sheath with respect to the tip member such that the sheath is spaced from the tip member, without deploying substantially the stent may be carried out after penetrating a ventricle wall of the heart.

Further advantages and characteristics of the present invention are described in the following description of examples and figures. The Applicant claims protection for any novel feature or idea described herein and/or illustrated in the drawings whether or not emphasis has been placed thereon.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the present invention, reference is made to the following description, taken in conjunction with the accompanying drawings, in which like reference characters refer to like parts throughout.

FIG. **1** is a schematic side view of a first embodiment of delivery catheter, with selected portions shown in cross-section.

FIG. **2** is a schematic section illustrating the proximal (handle) end of the delivery catheter of the first embodiment.

FIG. **3** is a schematic perspective view from above the proximal end (without the sheath represented).

FIG. **4** is a schematic perspective view from below the proximal end (without the sheath represented).

FIG. **5** is a schematic section showing a modified form of a handle usable with the first embodiment.

FIG. **6** is a schematic section illustrating a three-point bending test for the stem of the delivery catheter.

FIG. **7** is a schematic section illustrating one example of a distal end of the delivery catheter for the first embodiment.

FIG. **8** is a schematic section illustrating another example of a distal end of the delivery catheter for the first embodiment.

FIG. **9** is a schematic section illustrating a stage of partial opening of a distal end of a delivery catheter.

FIG. **10** is a schematic plan view illustrating indicia on the handle of the proximal end of a delivery catheter.

FIG. **11** is a schematic section illustrating in detail a removable stop.

FIG. **12** is a schematic side view of a cylindrical threaded element of one example.

FIG. **13** is a schematic side view of a cylindrical threaded element of a further example.

FIG. **14** is a schematic side view of an exemplary stent valve optionally used in connection with a delivery catheter according to the present invention.

FIG. **15** is a schematic section illustrating a second embodiment of a delivery catheter according to the invention.

DETAILED DESCRIPTION

In the following non-limiting detailed description, the same reference numerals are used to denote equivalent or similar features where appropriate. Further, reference is made to the accompanying drawings which form a part hereof, and in which is shown by way of illustration a specific embodiment in which the invention may be practiced. It is to be understood that other embodiments may be utilized and structural changes may be made without departing from the scope of the present invention.

FIGS. **1-14** illustrate a first embodiment of delivery catheter (also referred to as exemplary delivery device **1**) for implanting a stent (e.g., valve stent or stent-valve) **15**. The delivery catheter **1** comprises a proximal portion **1***a* to be held by an operator, a distal portion **1***b* for insertion into the body, and a stem or barrel portion **1***c* extending between the proximal and distal portions.

A sheath **2** may extend from the proximal portion **1***a* to the distal portion **1***b* where it may cover at least partly a stent **15** accommodated at a stent receiving portion **30**, and arranged on tube member **3**. Tube member **3** may further comprise a lumen adapted for the insertion of a guide wire **29**. The tube member **3** may extend through a handle **4** at the proximal portion **1***a*. The handle **4** may comprise an actuator for controlling and/or driving linear translation of the sheath **2** in the proximal and/or distal direction(s). Translation of the sheath in e.g., the proximal direction may uncover the stent to deploy or allow deployment of the illustrated form, the actuator comprises a manually operable rotary control (also referred to as a rotary handle or rotary handle member) **5**.

Two examples of the proximal portion **1***a* are illustrated in FIGS. **1-5**, and have similar features as follows. The handle **4** may comprise a cylindrical interior lumen into which the sheath **2** may be received. A connection member **13** may be

coupled to the proximal end of the sheath **2**. Optionally, the connection member **13** may comprise a valve **11**, which serves as inlet for a physiological saline solution used to flush the distal end of the catheter delivery device **1**. A rotary member **12** may be arranged proximally to the connection member **13**, e.g. to avoid the physiological saline solution to flow further towards the proximal end of the handle **4** and to rotationally support the various elements. A sliding member **10** may be arranged between rotary member **12** and a threaded cylindrical element **6**. A removable stop **9** may be arranged on the handle **4**, e.g. removably received in an aperture **32**. The stop **9** may function to prevent proximal movement of the sheath beyond a certain point, corresponding to partial release and/or deployment of the stent **15** without complete release and deployment. The stop **9** can engage the sliding element **10** to prevent the proximal movement of said element **10**, and of the sheath **2**, beyond said certain point. Only after removing the stop **9** the sheath **2** may be completely removed from the stent by moving the sheath to a most proximal position. Further, a fixation element **14** may be arranged in handle **4**. The fixation element **14** may serve to stabilise the tube **3** against longitudinal movement with respect to the handle **4**. Fixation element **14** may engage a channel (for example defined by a pulley profile) associated with the tube **3**.

The catheter delivery device **1** may further comprise gear means. The gear means include: a cylindrical threaded element **6** having a thread **7**; and a pin **8**. The cylindrical threaded element **6** is coupled to the rotary handle (rotary control) acting as the actuator. The pin **8** is fixed with respect to the handle **4**, and the pin **8** is engaged into thread **7**. Upon rotation of the actuator **5** the cylindrical threaded element **6** will also turn. As pin **8** is engaged into thread **7**, the rotation of the element **6** will result in a movement of the element **6** either in the proximal or in the distal direction, depending on which way actuator **5** is turned. As the cylindrical threaded element **6** is coupled via sliding element **10**, rotary element **12** and connection member **13** to the sheath **2**, the translational movement of the cylindrical threaded element **6** will be transmitted to sheath **2**.

The rotary handle **5** may be elongate in shape. The axial length may be longer than the diameter, for example, twice as large, or more. The rotary control may comprise an axial length of between about 3 cm to about 15 cm, 20 cm or 30 cm, including at least 3 cm, or at least 4 cm, or at least 5 cm, or at least 6 cm, or at least 7 cm, or at least 8 cm, or at least 9 cm, or at least 10 cm. Such sizes can facilitate intuitive gripping in the hand, for example, cupping the rotary control with the fingers and/or palm. The outer shape of the rotary control may be generally cylindrical and/or generally drum-like.

The tube **3** is optionally fitted at its proximal end with a luer valve **46**. The rotary handle **5** may include a socket or recess for accommodating, at least partly, the shape of the luer valve **46** when the rotary handle **5** is screwed or translated proximally. (Such accommodation is illustrated schematically in FIG. **2** although for the purposes of space in the drawing the rotary handle **5** is shown screwed towards the distal portion **1***b*).

The outer profile of the handle **4** may be generally cylindrical, optionally with one or more finger grips or recesses. Additionally or alternatively, the outer profile may include at least one bulbous portion **31**, e.g. partly spherical in shape. Such a portion **31** may allow more positive positioning of the handle in the hand according to individual preferences.

The bulbous **31** portion may have a radial height, compared to at least one adjacent surface of the handle, of between about 3 mm to about 10 mm, 15 mm or 30 mm, including at least 5 mm, at least 6 mm, at least 7 mm, or at least 8 mm. The bulbous portion **31** may have an axial extent of any of between about 15 mm to about 40 mm, including at least 20 mm; at least 25 mm; at least 30 mm. Additionally or alternatively to any of the above, the bulbous portion **31** may have an axial extent of: not greater than 40 mm; not greater than 30 mm; not greater than 35 mm.

The bulbous portion **31** may have a frusto-spherical shape. The bulbous portion **31** may have a radius of curvature of any of between about 10 mm to about 40 mm, 50 mm or 60 mm, including at least 15 mm; at least 20 mm; at least 23 mm. Additionally or alternatively to any of the above, the radius of curvature may optionally be: not greater than 60 mm; not greater than 50 mm; not greater than 40 mm; not greater than 30 mm; not greater than 25 mm; not greater than 23 mm.

Such arrangements of bulbous portion **31** can provide a highly intuitive and versatile tactile positioning guide for the handle. The guide may fit snugly in the palm of the hand, and/or be cupped comfortably by the fingers. The guide may also provide a suitable surface for gripping with the fingers to apply axial force to the handle. The guide may also provide substantially the same feel to the operator whatever the rotational orientation of the handle **4** around the catheter axis.

FIGS. **7** and **8** show two examples of the distal portion **1***b* of the catheter delivery device. The examples are similar and differ only in terms of the nature of the sheath **2**. In both examples, the sheath **2** comprises a constraining portion **2***a* for covering a stent at the stent receiving portion **30**. The constraining portion **2***a* may be an integral extension of the sheath **2**, or it may be a reinforced sheath part bonded or otherwise permanently attached to the sheath **2**. In the illustrated form, the constraining portion **2***a* has substantially the same outer diameter as the sheath **2** (at least no difference larger than 10%, or more preferably no larger than 5%). Such constant size may facilitate sealing against blood leakage where the catheter penetrates the wall of a blood vessel or the heart wall, even when no introducer is used. For example, a good seal may be achieved by advancing the distal portion **1***b* through an undersized aperture in the ventricle wall. The elasticity of the ventricle wall permits passage of the distal portion **1***b* through the undersized aperture, while tightly engaging the outer surface.

The stent **15** may be coupled to the tube member **3** by coupling means (also referred to as a stent holder) **16**, for preventing axial movement of the stent until the moment of full release and/or full deployment. The tube member **3** may itself be reinforced over at least a part of its length by a dual wall structure (e.g., one tube nested within another, and coupled to function as a single unit). As evident at **3***a*, the dual wall structure may terminate distally of the coupling means **16**. At the most distal tip, the catheter delivery device **1** may comprise a tip element **20**, for example having a conical from. The tip element **20** may allow for an easy insertion of the delivery catheter.

In the form illustrated in FIG. **7**, the sheath **2** comprises (in the stem portion **1***c* of the delivery catheter) an outer tube and an annular spacer member **2***c* disposed between the outer tube **2** and the tube member **3**. The annular spacer member **2***c* may be segmented and may serve to prevent kinking of the outer tube **2***b*. The outer tube **2***b* may be coupled to the constraining portion **2***a* by means of an

intermediate bridge **2***b*. The bridge **2***b* may optionally form part of, or be coupled to, the annular spacer member **2***c*.

In the form illustrated in FIG. **8**, the sheath **2** comprises a thicker wall tube without an annular spacer member. The thicker wall tube resists kinking.

Referring to FIG. **6**, in some embodiments the stem portion **1***c* may have a flexure characteristic such that, in order to produce flexure displacement of 10 mm using a three-point bending test, the applied force may be (i) between 2.5 and 3.5 N (inclusive range), or (ii) between about 6.0 and 7.5N (inclusive range), or (iii) generally between about 2.5 and 7.7N (inclusive range). The three-point bending test may comprise supporting the stem portion at two spaced apart positions **33**, and observing the degree of bending displacement when a force is applied, in a diametrically opposed direction to the supports, at a position **34** midway between the spaced apart support positions. The spacing between the support positions may be about 16 to about 20 times the outer diameter of the stem. The flexure displacement may be measured as a displacement with respect to a condition of the stem **1***b* when no force is applied (e.g. substantially straight, or with only slight flexure). The applied force range (i) may optionally be associated with a spacing of 20 times the outer diameter. The applied force range (ii) may optionally be associated with a spacing of 160 mm and/or an outer diameter of 9.8 mm (+−0.5 mm) and/or a spacing that is about 16 times the outer diameter.

Such a flexure characteristic may be advantageous in meeting the conflicting desirata of flexibility and support. Especially in the case of a transapical approach, the delivery catheter has to provide sufficient support to be able to advance the distal end through a relatively tight access aperture in the ventricle wall. It is desirable that the aperture in the ventricle be as small as possible, to reduce risk of interference with the distribution of natural electrical pulses essential to healthy heart operation, and/or reduce the invasiveness of the procedure on the heart tissue, and/or facilitate easier closing after the procedure to restore the integrity of the ventricle wall, and/or facilitate the patient's recovery after the procedure. It is desirable to create the access aperture undersized, and rely on the elasticity of the heart muscle tissue to allow the aperture to expand elastically to accommodate passage of the delivery catheter therethrough. Such a tight fit can also provide a self-seal against blood leakage, the procedure being carried out while the heart remains beating to pump blood around the circulatory system. The delivery catheter also has to be flexible to accommodate a non-straight delivery path through the heart and the existing valve. Different surgeons have different preferences for the entry path through the anatomy to the heart. The flexure characteristic defined herein can provide a surprisingly good balance between the support and flexibility.

Referring to FIGS. **7-9**, in some embodiments, a method is used for selectively enhancing flexibility of the distal portion **1***b*. As can be seen in FIGS. **7** and **8**, in the closed position of the sheath **2**, the sheath **2** may abut a confronting surface of the tip element **20**. Such abutment may support stably the tip element **20** when the tip **20** is advanced through an undersized aperture in the ventricle wall. Once inside the heart, and/or after having advanced at least partly though the valve to be replaced, it may be desirable to allow the tip element **20** more freedom to flex. Referring to FIG. **9**, in the some embodiments, this is achieved by displacing the sheath **2** partly (as indicated by arrow A), so that it no longer abuts the tip element **20** (as indicated at B), but is not sufficiently displaced to allow substantial deployment of the stent **15**. Displacing the sheath **2** away from the tip element **20** removes the direct support, thereby permitting the tip **20** greater freedom to flex (indicating by arrow C). Following such partial or limited displacement, the distal portion **1***b* may be further advanced into the heart and/or ascending aorta, while benefiting from the enhanced flexibility of the tip, until the distal portion **1***b* arrives at a desired position for deployment of the stent **15**. Thereafter, the sheath **2** is displaced further in the direction of arrow A to release the stent **15**.

In some embodiments, the handle **4** carries an indicator **35** for indicating, to the operator viewing the proximal portion **1***a* of the catheter, the rotational orientation of the stent **15** carried at the distal portion **1***b*. Depending on the design of stent **15**, it may be desirable to implant the stent with a certain rotational orientation with respect to the local anatomy. The stent **15** may have a non-predetermined, or variable, rotational orientation with respect to the stent holder **16** and/or to the handle **4**. However, although the orientation may be non-predetermined, it may remain constant once the stent **15** has been loaded into the stent containing region **30** and constrained by the sheath **2**. Once loaded, the operator can set the indicator **35** to indicate the orientation of the stent **15** at loading. The indicator **35** enables the operator to known the orientation of the stent, even when the distal portion **1***b* is hidden with the anatomy. The procedure may be carried out using medical imaging from which the stent orientation may also be derivable, but the presence of an indication directly on the handle **4** provides the operator with additional information to avoid any ambiguity.

In the illustrated forms, the indicator **35** comprises a ring or collar rotatable around the axis of the handle and/or delivery catheter. The indicator **35** is manually settable by manual rotation. A friction member **36** (e.g. an O-ring of elastomeric material) frictionally resists rotation of the indicator **35**, so that it is unlikely to slip out of the set position in use. In some embodiments, the indicator **35** carries or comprises visual indicia **37**. For example, the indicia **37** may be printed on the indicator **35**, or comprise distinct elements (e.g. as in FIG. **4**).

In some embodiments, the stent **15** comprises plural commissures associated with the shape of the stent and/or the valve. The indicator **35** may bear plural indicia **37**, one for each commissure. By way of example only, FIG. **14** shows one example of a stent **15** optionally used in connection with a catheter delivery device **1** of the present invention. The stent **15** has a distal end **26**, a proximal end **27** and comprises stabilization arches **21**, commissural posts **22**, upper anchoring crown **23**, lower anchoring crown **24** as well as attachment elements **25**. The stabilization arches **21** serve to stabilize the stent **15** in a blood vessel, preferably the aorta, during deployment. Typically, three leaflets of a replacement heart valve are attached to commissural posts **22**. The upper anchoring crown **23** serves to attach the stent **15** in the aortic side of a heart valve, while the lower anchoring crown serves to attach the stent **15** on the ventricular side of the heart valve. Attachment means **25** enable the removable attachment of the stent **15** to the stent holder **16** of the catheter delivery device **1**. The illustrated stent **15** has three commissures, and the indicia **37** may comprise three respective indications.

In some embodiments, the delivery catheter **1** comprises feedback means for providing an indication to the operator of: (i) the sheath position (e.g. degree to the which the sheath is displaced open); and/or (ii) release state of the stent **15**;

and/or (iii) when the sheath reaches a predetermined release position associated with a release phase of the stent.

In some embodiments, the feedback means comprises a visual indication **38** on the handle. Referring to FIG. **10**, the indicator **38** comprises indicia on a portion of the surface of the handle **4** that is selectively covered or exposed, depending on the position of the rotary control **5**. The threaded connection between the rotary control **5** and the handle **4** results in the rotary control **5** translating linearly (as indicated by arrow D) as the rotary control **5** is turned. The rotary control **4** translates linearly with the sheath **2**. The linear position of the rotary control **5** thus provides a representation of the linear position of the sheath **2**. The indicator **38** is provided at a position on the handle **4** such that the indicator **38** is progressively exposed by the linear translation of the rotary control **5**. The indicator **38** may for example, comprise a scale indicating the extent to which the sheath **2** is open at the distal portion **1***b* (for example, represented by a triangular form, the spacing between the two long sides indicating the extent to which the sheath is open). Additionally or alternatively, the indicator **38** may comprise one or more marks **39** indicating when a certain release position of the sheath **2** has been achieved. For example, if the stent **15** has the form illustrated in FIG. **14** and described above, it may be intended for release in plural steps or phases S**1** and S**2**+ (which may be S**2**+S**3** in FIG. **14**). A first step S**1** corresponds to the release of the stabilization arches **21** and, optionally, the upper crown **23**. A second step (S**2**+) includes release of the lower crown **24** and, optionally, the attachment elements **25**. The indication marks **39** enable the operator to see when the respective release point of each step or phase is expected to occur, and to control the delivery catheter **1** accordingly.

The indications **38** and/or **39** may be repeated at plural positions around the circumference of the handle **4**, so that at least one indication **38**/**39** may always be in view irrespective of the rotational orientation of the handle **4**. Additionally or alternatively, the indications may be circumferentially continuous (e.g., as represented by the circumferential broken lines at **39**).

As mentioned previously, the removable stop **9** may also provide tactile feedback to the operator about when the sheath reaches the end of the first step S**1**. The removable stop **9** may be configured to obstruct further linear translation of the sheath **2** once the end of the first step S**1** has been reached.

In a simple form (e.g. as in FIG. **5**), the removable stop **9** may consist of a pin having a friction member (e.g. an O-ring of elastomeric material) at its end insertable into the aperture **32**. In a more enhanced form (FIGS. **1**-**4** and **11**), the removable stop **9** may consist of first and second parts **40** and **41** that are displaceable relative to each other. The first and second parts **40** and **41** may be arranged one part for bearing a removal force, and the other part for bearing at least a portion of an opposite reaction to the removal force. Such a stop is highly advantageous by reducing, to a large extent, the reaction to the removal force applied to the delivery device itself. For example, if using a pull-out friction-fit pin as in FIG. **5**, the reaction force is applied to the delivery catheter, and the operator has to support the delivery catheter with one hand in order to support the reaction to the force applied with the other hand to pull-out the pin. However, minor movement or perturbation of the delivery catheter can sometimes cause accidental release of the stent or displace the stent out of a desired implantation position. In contrast, a two-part configuration **40**, **41** of the removable stop **9** can reduce significantly the reaction to the removal force experienced by the delivery catheter. The first and second parts **40** and **41** may be substantially coaxial about an axis of the stop, and slidable relative to each other along said axis. One part **40** may comprise a pull-out friction-fit within the aperture **32** of the handle **4**, and the other part **41** may comprise a pusher for pushing against the delivery device. The first part **40** may carry a friction member **40***a* (similar to that described above). The second part **41** may have a pusher tip **41***a*. The first and second parts **41** may have spaced apart manually engageable portions that, when squeezed one towards the other (as indicated by the arrows **42** in FIG. **9**) are configured to release the stop **9** from the handle **4**.

FIGS. **12** and **13** show different examples of the cylindrical threaded element **6** usable in the first embodiment. The example of FIG. **12** is shown used in the handle of FIG. **2**, and the example of FIG. **13** is shown used in the handle of FIG. **5**, but this selection is merely for the sake of illustration, and either example of element **6** may selected for each handle as desired.

Both examples of cylindrical threaded elements **6** comprise an internal lumen **18** through which tube member **3** and/or a guide wire may be inserted. Connection element **17** allows to connect the cylindrical threaded element **6** to an actuation means such as the rotary handle **5**. An additional axle member **19** allows to rotationally connect member **6** to further elements and/or to the handle **4**. The cylindrical threaded element **6** comprises thread **7**. The thread **7** may have any suitable cross-section form, such as rectangular (as in FIG. **13**) or rectangular with an additional guide-groove **43** (FIG. **12**) for co-operating with a tip of the pin **8**.

The element **6** is configured to drive linear translation of the sheath **2** between operative closed and open positions, over a full operative range of linear movement, by three turns or less about the catheter axis. In FIG. **12**, the full operative range of movement is achieved by two turns or less. In either case, a friction member **45** (FIG. **2**) may optionally be provided to resist self-rotation that might otherwise occur when using a relatively coarse thread **7** to achieve such translation for few rotational turns. The friction member **45** may be positioned between confronting surfaces of the rotary control **5** and the handle **4**. For example, the friction member **45** may be mounted in a groove on the outer surface of the handle **4** for bearing against an inner surface of the rotary control **5**. The friction member **45** may comprise an O-ring of elastomeric material. Such an arrangement can provide reliable and reproducible control over the amount of friction between the handle **4** and the rotary control **5**, and facilitate simple construction.

In the example of FIG. **12**, thread **7** has a substantially uniform thread pitch. Such a thread **7** produces uniform gearing between the rotary control **5** and the sheath **2** over the entire range of movement. In the alternative example of FIG. **13**, thread **7** has three sections with different thread pitches H**1**, H**2** and H**3**. The different thread pitches H**1**, H**2** and H**3** allow having different gearing ratios between the movement of the actuation means **5** and the movement of the sheath **3**. Alternatively, the member **6** may also comprise further sections with yet different thread pitches. For example, further intermediate sections may define a progressive incremental change in thread pitch (e.g., between H**1** and H**2**) in order to avoid large step changes or discontinuities in the thread smoothness. The different thread pitches may be in the range of about 5 mm to about 50 mm, including, for example, about 10 mm to about 40 mm, about 15 mm to about 30 mm, or about 5 mm to about 35 mm.

Table 1 shows an example of different thread pitches which may be used for the thread **7** of the cylindrical threaded element **6**:

TABLE 1

Thread section	Thread pitch [mm]
H1	30
H2	10
H3	15

Referring to the different thread pitches H**1**, H**2** and H**3** of thread **7** as shown in FIG. **13**, and the stent example shown in FIG. **14**, the thread pitch H**1** is configured such as to provide a first transmission or gear ratio when moving the distal end of the sheath **3** along the first portion S**1** of the stent **15**. Accordingly, the thread pitch H**2** is arranged such as to provide a different second transmission or gear ratio, such as a lower second transmission or gear ratio when the distal end of the sheath **2** moves along portion S**2** of the stent **15**. Finally, thread pitch H**3** may be adapted such as to provide yet a different third transmission or gear ratio when the distal end of the sheath **2** moves along the portion S**3** of the stent **15**. The diagrams (a) and (b) in FIG. **4** illustrate two alternatives examples for the portions S**1**, S**2** and S**3**; it will be appreciated that other configurations are also possible.

FIG. **15** shows an alternative embodiment 1 of the catheter delivery device **1** according to the present invention. A stent attachment region **28** is located at the distal end of the catheter device, holding the catheter **15**. At its most distal tip, the conical section **14** is arranged. The sheath **2** extends from the handle **4** located at the proximal end of the catheter device **1** to the distal end. As such, the sheath **2** may at least partially or completely circumferentially cover the stent **15**. Tube member **3** extends along the entire length of the delivery device **1** and comprises a guide wire **29**. In this embodiment, the actuation means are configured as trigger element **5**. The handle **4** comprises a pistol grip **31** to enable a safe and easy handling of the catheter device by an operator. The device **1** further comprises braking means **9** configured as cylindrical, optionally self turning, threaded element. The threaded element may be analogous to the threaded element **6** as shown on FIG. **4**. Said threaded element may optionally include a thread **7** with different thread pitches, which applies a resistance to the actuation means **5** having a braking effect. When the trigger **5** is pulled back, the sliding member to which the sheath is attached abuts against an abutment surface. Upon further actuation of the trigger, the treatment element is rotated due to its self turning design. If the pitch becomes lower, the force which has to be applied by the trigger becomes bigger or self turning becomes impossible so that the movement is stopped. Alternatively, the thread pitch may be uniform, and the braking effect (increased) resistance is created by the sliding member to which the sheath is attached abutting the thread partway along the reciprocal run of the sliding member. For example, the sliding member may slide in a proximal direction freely or substantially "unbraked" over a first movement range to a predetermined position without contacting the thread; when the sliding member reaches the predetermined position, the sliding member abuts the thread, such that the braking effect is applied for the remainder of the range of proximal movement.

Definitions

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, suitable methods and materials are described below. All publications, patent applications, patents, and other references mentioned herein are incorporated by reference in their entirety. In the case of conflict, the present specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only not intended to be limiting. Other features and advantages of the invention will be apparent from the following detailed description and claims.

For the purposes of promoting an understanding of the embodiments described herein, reference will be made to preferred embodiments and specific language will be used to describe the same. The terminology used herein is for the purpose of describing particular embodiments only, and is not intended to limit the scope of the present invention. As used throughout this disclosure, the singular forms "a," "an," and "the" include plural reference unless the context clearly dictates otherwise. Thus, for example, a reference to "a device" includes a plurality of such devices, as well as a single device.

Throughout this application, the term "about" is used to indicate that a value includes the standard deviation of error for the device or method being employed to determine the value.

Reference to numeric ranges throughout this specification encompasses all numbers falling within the disclosed ranges. Thus, for example, the recitation of the range of about 1% to about 5% includes 1%, 2%, 3%, 4%, and 5%, as well as, for example, 2.3%, 3.9%, 4.5%, etc. In some instances in the specification the term "inclusive" is used to reiterate this point.

The use of the term "or" in the claims is used to mean "and/or" unless explicitly indicated to refer to alternatives only or the alternatives are mutually exclusive, although the disclosure supports a definition that refers to only alternatives and "and/or."

As used in this specification and claim(s), the words "comprising" (and any form of comprising, such as "comprise" and "comprises"), "having" (and any form of having, such as "have" and "has"), "including" (and any form of including, such as "includes" and "include") or "containing" (and any form of containing, such as "contains" and "contain") are inclusive or open-ended and do not exclude additional, unrecited elements or method steps.

The invention claimed is:

1. A delivery catheter configured to deliver a stent, the delivery catheter comprising:

a distal end and a proximal end, the distal end including a stent attachment region adapted to receive a stent, the delivery catheter further comprising a handle at its proximal end and at least one sheath configured to at least partially circumferentially cover the stent to retain the stent in a collapsed configuration, the at least one sheath being coupled at a proximal end to an actuator located in or on the handle and configured to move the at least one sheath along the stent,

wherein the actuator comprises a manual rotary control associated with a helical threaded element than causes linear translation of the manual rotary control relative to the handle as the manual rotary control is turned, the handle further comprising indicia positioned so as to be progressively exposed or covered by the manual rotary control according to a linear position of the manual

rotary control, the indicia indicating an extent of displacement of a sheath at a proximal portion,

wherein the threaded element is configured and adapted to present a first level of resistance to movement of the actuator relative to the handle when the distal end of the at least one sheath has reached a first defined position on the stent during proximal and/or distal movement of the at least one sheath along the stent, and to present a second level of resistance to movement of the actuator relative to the handle when the distal end of the at least one sheath has reached a second defined position on the stent during proximal and/or distal movement of the at least one sheath along the stent, wherein the first and second levels of resistance are different.

2. The delivery catheter according to claim **1**, wherein the manual rotary control is arranged such as to move the sheath in the distal and/or proximal direction(s) along an operative range of movement in response to rotation of the manual rotary control through three turns or less around a longitudinal axis of the delivery catheter.

3. The delivery catheter of claim **2**, further comprising a friction member configured to frictionally resist rotation of the manual rotary control.

4. The delivery catheter of claim **1**, wherein the manual rotary control is rotatable around the longitudinal axis of the delivery catheter and arranged such as to move the sheath in the distal and/or proximal direction(s), the manual rotary control having a longitudinal length of at least 4 cm.

5. The delivery catheter of claim **4**, wherein the manual rotary control is elongate in the direction of the longitudinal axis of the delivery catheter.

6. The delivery catheter of claim **1**, wherein the delivery catheter comprises a valve stent, wherein the valve stent comprises first and second portions configured to engage opposite sides of a native aortic valve annulus; and wherein the indicia are configured to indicate sheath displacement with respect to a first step of deploying the first stent portion and a second step of deploying the second stent portion.

7. The delivery catheter of claim **1**, wherein a stem portion of the delivery catheter extending between said distal and proximal portions has a flexure characteristic such that, in order to produce flexure displacement of 10 mm using a three-point bending test, an applied force is between 2.5 and 7.5 N.

8. The delivery catheter of claim **1**, wherein the handle further comprises an indicator rotatable about the longitudinal axis of the delivery catheter, the indicator being positionable to indicate a rotational orientation of a stent with respect to the handle.

9. The delivery catheter of claim **8**, wherein the indicator is manually settable.

10. The delivery catheter of claim **8**, wherein the delivery catheter further comprises a stent which includes a valve having valve leaflets and associated peripheral commissures, and wherein the indicator comprises indicia indicating the rotational orientation of at least one of the commissures.

11. The delivery catheter of claim **1**, wherein the handle comprises a bulbous portion intermediate distal and proximal ends of the handle, the bulbous portion configured to provide a tactile positioning guide to an operator's hand.

12. The delivery catheter of claim **1**, wherein the delivery catheter comprises a valve stent which is a self-expanding stent.

13. The delivery catheter of claim **1**, wherein delivery catheter comprises a valve stent and a tactile feedback guide configured to warn an operator that the distal end of the sheath is about to move over the proximal end of the stent.

* * * * *